From:	Vigil, Kenny C, DOH
To:	Sundberg, Andrea, DOH
Subject:	FW: [EXT] Manufacturers Regulatory Changes
Date:	Wednesday, October 16, 2019 8:18:14 AM

Not sure if you got this, but want to double check.

From: Derek Young [mailto:derek@organabrands.com]
Sent: Tuesday, October 15, 2019 2:24 PM
To: Gonzales, Martinik, DOH <Martinik.Gonzales@state.nm.us>; Vigil, Kenny C, DOH <KennyC.Vigil@state.nm.us>; Zurlo, Dominick, DOH <Dominick.Zurlo@state.nm.us>; Peralta, Matthew, DOH <Matthew.Peralta2@state.nm.us>
Cc: Bryan Sullivan <bryan.s@organabrands.com>; Siobhan Sullivan <siobhan@organabrands.com>
Subject: [EXT] Manufacturers Regulatory Changes

Dear Directors and employees of the New Mexico Medical Cannabis Program,

We are writing with amicable intent and great concern for upcoming changes and amendments to the state approved and licensed manufacturers of the NMMCP program. After our meeting with the NM DOH to review proposed changes and amendments to the current NMCP rules and regulations for 2019/2020 year, we would like to speak to the points that were covered in this meeting:

- Licensing Fee increase of 500% ($1-5k) without any understanding of what this increase will benefit. We were told you captured details from other states programs but failed to note what their fees covered, including a plant count for those manufacturers and any benefits/protection this offered to the current licensed and state approved manufacturers. Such an increase with only serves the state and not the patients of the NMMCP program or the producers/manufacturers.

- Q/A testing for pesticides and heavy metals at the producer level is absolutely necessary. The fact these weren't required thus far is shocking considering all issues facing manufacturers.

- The sample size being requested for testing at 25 grams is absolutely not possible. There are many producers that provide small amounts of product to us and once processed, yields could be as low as 25 grams or as high as 100. There are so many factors that come into play with the actual amount of finished product that you would be asking manufacturers and producers to sacrifice more than what their actual return would be. 1-3 grams is standard in any other medical or recreational market. 25 grams would impose hardship and product loss for the LNPP's, manufacturer's. Why are all other proposed regulations based on other states medical and recreational cannabis programs but testing is based on national pharmacopeia statistics?

- Speaking to the additives section you covered. Although not much was given to this section, we feel it absolutely necessary to cover what you noted. You spoke about any non-cannabinoid additive being introduced to the oil EXCEPT for food-grade terpenes. Here is the issue, food grade terpenes have NOT been evaluated for inhalation. Botanical Terpenes have. Neither contain cannabinoids so why is one, that is clearly not safe to inhale, being excused from this ban? We are confused as to why this particular proposed rule seems to benefit one manufacture over the other. Botanical terpenes are plant derived and have been scientifically evaluated for inhalation and used to copy or mimic, synthetically, cannabis terpenes. Not flavor the cannabis or dilute or cut or increase potency. We are quite aware of the current concerns facing the vaping industry and fully understand that not one case has been solely tied to the regulated market. All manufacturers in the NMMCP program pride themselves/ourselves on producing clean medicine and have not faced any allegations over black market, unregulated product, regulated product or tested product, both THC derived and nicotine. We will not sit back and allow uneducated decisions to affect our clean, tested, regulated medicine and cause unnecessary hype, hysteria or false allegations/bans to impede the great work we do.

- The universal "THC" stamp is completely agreed upon. The proposed "THC NM" stamp that would require all molds to be replaced is not considered practical considering all other proposed additional fees the manufacturers would face. Other states do not require their specific state name or initial to be located anywhere on the product, only the "THC" stamp. Until we go recreational and new rules and regulations are put in place, we shouldn't put the cart before the horse and impose a hardship to the manufacturers, considering the already proposed changes.

- Universal labeling that you proposed would be welcomed if the producer could utilize some kind of exit bag that noted the "universal" language that needs to be noted on the product (except potency, batch# etc.) to take the burden off the manufacturer to cover the physical product with this labeling in the font proposed. Same idea at the pharmacy. The general information noted on the actual product is the patient name, medication name, prescription number, retailer info, product strength and directions of use along with food direction. They give you an insert with a page of all other noted information on the drug. To impose this on manufacturers to label the product in accordance with the label proposed will only create more packaging and more waste.

We all welcome change and understand, in this always dynamic industry, that we must be ready and prepared to handle growth and to support a clean and healthy option to patients and consumers. We are open to further discussions on changes and feel that any proposed rules you outlined would not be affective or productive for any of us involved, including the current patients of the NMMCP who would ultimately feel the brunt of excess fees, testing, labeling and bans thus continuing to force them and future consumers to the black market.

Sincerely and Respectfully,

Derek R. Young
Bryan T. Sullivan

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Ultra Health®

Andrea Sundberg
NM Department of Health
Medical Cannabis Program
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Re: Comments on Proposed Rules NMAC 7.34.4; Public Hearing November 22, 2019

Dear Department of Health,

The purpose of this letter is to provide New Mexico Top Organics-Ultra Health's ("Ultra Health's) comments upon proposed amendments to various rule sections of the Department's Medical Cannabis Program rules at Parts 7.34.4 NMAC, which are to be considered at a public hearing scheduled for November 22, 2019.

NMAC 7.34.4.7; Definitions

Although the Department of Health ("DOH") has made some effort in its proposals to make reference to statutory authority, there are several definitions in NMAC 7.34.4.7 that still, inexplicably, do not match or track statutory definitions. The Lynn and Erin Compassionate Use Act, NMSA 1978 § 26-2B-3, contains 28 different definitions. The inclusion of so many definitions within the statute indicates the Legislature wished to take care to define and direct the Medical Cannabis Program. Despite the Legislature's care, DOH has continued to change the explicit direction of the Legislature.

The regulatory definitions of "cannabis courier," "cannabis manufacturer," "cannabis producer," "manufacture," and other terms do not match the definitions set out in statute. For example, "cannabis courier" in statute is a person "licensed" by DOH, whereas in regulation it is a person "approved" by the department. Likewise, "cannabis manufacturer" in statute is an entity "licensed" by DOH, whereas "manufacturer" in regulation is a person "approved." A "cannabis producer" in statute is "a person that is licensed by the department to possess, produce, dispense, distribute and manufacture cannabis and cannabis products and sell wholesale or by direct sale to qualified patients and primary caregivers," but a "licensed producer" in regulation is "a person or entity licensed to produce medical cannabis." "Manufacture" in statute means "to prepare a cannabis product," but "manufacture" in regulation means "to make or otherwise produce cannabis-derived product or concentrate."

The statute contains definitions for "cannabis establishment," "cannabis product," "cannabis testing facility," "hemp," "license," "licensee," "produce," and others, but the regulations do not contain these definitions.

As DOH knows, the issue of DOH's regulatory authority has arisen several times in litigation regarding the proper implementation of the Compassionate Use Act. When DOH uses different definitions than the statute does, the difference sows confusion among medical cannabis businesses and patients. The differences also breed an atmosphere of distrust between medical cannabis business and DOH, because the businesses cannot serve two masters—both the statute and the regulation.

It is both legally proper and beneficial to the business-DOH relationship to ensure that regulations match statutory language. It is beneficial to the business-DOH relationship because it creates consistent standards and eliminates confusion. It is legally proper because "When an agency construes a statute that governs it, the court will accord some deference to the agency's interpretation," but "we are less likely to defer to an agency's interpretation of the relevant statute if the statute is clear and unambiguous, as it is in this case," and "if statutory construction is not within the agency's expertise, this Court should afford little, if any, deference to the agency on issues of statutory construction." *Marbob Energy Corp. v. New Mexico Oil Conservation Commission*, 2009-NMSC-013, ¶ 6-7, 206 P.3d 135. Additionally, between a statute and a regulation, the statute trumps the regulation. "When a statute and a regulation conflict, the statute prevails." *Gallegos v. State Bd. of Education*, 1997-NMCA-040, ¶ 23, 123 N.M. 362.

Certainly, DOH may add more definitions to its regulations than appear in statute. However, DOH's attempts to change the explicit wording of the statute is improper and also inexplicable. The regulatory definitions should exactly match any definition given by statute.

NMAC 7.34.4.8(Z); Geographical Regions

This part of the proposed regulations states, "The department may additionally restrict the licensing of non-profit producers to applicants that commit to production and distribution of usable cannabis in specific geographical locations of the state."

Commenter Ultra Health believes strongly in serving rural areas of New Mexico, and for that reason, Ultra Health has opened dispensaries in 13 of out 33 counties in New Mexico.

Although DOH certainly expresses the right sentiment with this proposed regulation, its effect is unfortunately ambiguous. It is not clear whether this "restriction" applies to *new applicants* for a license or *applicants for re-licensure*. That is, will DOH consider the commitment to underserved areas only for applicants seeking entirely new licenses, or will DOH consider the commitment when it re-licenses entities who have held licenses for years? If DOH applies this criterion to already-licensed entities who are going through re-licensure processes, this criterion could result in closure of smaller producers and could disrupt production and patient access.

Additionally, the placement of this proposed regulation is odd. NMAC 7.34.4.8(F) already sets out "factors considered" in "determining the number of licenses" and which entities shall be licensed. If DOH is concerned about applicants' commitments to underserved areas, then it could add that as a "factor considered" in granting license applications in the first place.

NMAC 7.34.4.9; Minimum Standards for Production

Commenter Ultra Health believes the sentiment expressed by NMAC 7.34.4.9 is correct, but the vagueness of some of the provisions here will result in unworkable standards. Ultra Health believes that the general level of professionalism in New Mexico's medical cannabis industry should be increased, and Ultra Health believes that cannabis businesses should strive for high levels of quality control and technical accomplishment.

However, the level of strictness of 7.34.4.9 is positively draconian and may very well drive smaller producers out of business due to the costs of compliance. For example, 7.34.4.9(A)(1) requires compliance with "zoning, occupancy, licensing, and building codes." Many producers in New Mexico rent their premises and have little control over building codes. Placing the burden on producers means producers will have to spend significant sums on building code reviews and renovations *in rented premises*.

There are also vagaries that produce absurd results. For example, the requirement that all "equipment, implements, and fixtures shall be used exclusively for the production of cannabis" means that a microwave in an employee break room would be disallowed, and that the computer used to run BioTrack is disallowed. One provision here requires production to be conducted "in a manner that does not allow cross-contamination from chemical or biological hazards," without a precise definition of "hazards." Such innocuous substances as water or oxygen can quickly become hazards under specific conditions.

NMAC 7.34.4.9(A)(12)

One particularly problematic provision is NMAC 7.34.4.9(A)(12), requiring that "floors, walls, and ceilings are constructed in such a manner that they are washable, wipeable, and non-absorbent, and can be kept clean, and kept in good repair." This requirement is simply unworkable for the medical cannabis industry. It seems to have come from a food manufacturing setting, but DOH forgets that a medical cannabis facility combines an agricultural operation with a manufacturing operation.

Some producers still grow outdoors, in soil, and soil can never be made non-absorbent. Outdoor growers are also quite incapable of having "washable" ceilings, in that their ceiling is simply open sky.

Ultra Health itself grows in greenhouses with floors made of gravel; the purpose of the gravel is to allow excess water to flow away. The alternative—a non-absorbent floor—would mean that the plants are watered and the excess water simply stands in pools on concrete. Standing water is a much more dangerous breeding ground for contaminants than gravel is.

If Ultra Health is made to renovate its greenhouses with non-absorbent flooring, it will have to pour concrete on the floor of the greenhouses; this will put the greenhouses out of operation for quite some time. It will also require Ultra Health to change its growing systems to install some method for drainage, so that water will not pool on the concrete floor. This will be another investment and will also take the greenhouses out of operation for a significant period.

Ultra Health understands DOH's purpose with this requirement: to ensure cleanliness. However, DOH must remember that cannabis is, first and foremost, an agricultural product grown in agricultural conditions. The manufacturing side is more akin to the food production field, from which DOH obviously took these regulations.

DOH must separate the growing from the processing and finishing. The growing stages should be subject to agricultural standards, while the processing and finishing should be subject to manufacturing standards. DOH has combined the strictest part of both worlds, and in doing so, has jeopardized the very existence of many producers.

NMAC 7.34.4.9(A)(3)

This provision requires a producer to ensure "that no cannabis plants other than those grown pursuant to the non-profit producer's production license from the department are grown on the premises of the non-profit producer, including but not limited to hemp plants."

This provision effectively prohibits a producer from co-housing medical cannabis plants and industrial hemp plants on the same campus. Now, the first problem here is one of vagueness: what is a "premises?" Are premises defined by the address of a property? By who owns which parcel of an addressed property? By fences? By walls?

The larger problem is that DOH exceeds its statutory authority by claiming power to regulate the location of hemp. When the Legislature legalized the cultivation of industrial hemp, it gave regulatory authority over hemp to the Department of Agriculture. See NMSA 1978 § 76-24-2 (2017). The Department of Health, on the other hand, has never been given any kind of regulatory authority over hemp.

DOH is now attempting to regulate the locations where hemp may be grown, and in doing so, DOH is usurping the regulatory authority of the Department of Agriculture. DOH can exercise limited control over where medical cannabis may be grown, but it cannot exercise control over where hemp is grown.

Furthermore, the limited ability of DOH to control where medical cannabis is grown does not include placing restrictions on what other crops may be grown alongside medical cannabis. NMSA 1978 § 26-2B-7(A)(6) provides that "production facilities" must be "housed on secured grounds and operated by licensees" and that other facilities must be "not within three hundred feet of any school, church or daycare center."

Now, as DOH will recall, Ultra Health obtained a writ of mandamus from the Thirteenth Judicial District Court in case D-1329-CV-2018-01854. That writ held that DOH could not

place location restrictions on dispensaries other than the 300-feet rule. In a larger sense, the writ stands for the proposition that DOH cannot restrict land use of producers in a manner not set out in statute.

Here, statute sets out that production facilities must be secure, but it does not otherwise restrict how producers use their property. The statute does not specify indoor or outdoor grows, does not require labeling of the property to passers-by, and does not prohibit colocation of other activities.

Ultra Health believes that DOH, by prohibiting colocation of hemp and medical cannabis, is going beyond the bounds of statute. Now, Ultra Health would not oppose a regulation that required some kind of segregation of hemp and medical cannabis within a premises or campus, such as with walls, fences, and signage. This type of segregation would be done only to ensure that the respective regulators of DOH and DOA could tell the plants apart.

NMAC 7.34.4.10; Testing

Once again, Ultra Health applauds the sentiment of NMAC 7.34.4.10—to increase the quality of medical cannabis produced in New Mexico—but must express serious reservations with the rule based upon potentially devastating effects.

Impossibility of Testing

The rule requires much more testing than is currently required. Currently, there are one-and-a-half laboratories in New Mexico that handle medical cannabis. Ultra Health says "half" of a laboratory because Scepter Lab laboratory is located in Santa Fe. The other laboratory, Rio Grande Analytics, is located in Las Cruces. It has been Ultra Health's experience that when couriers travel with medical cannabis to Las Cruces, federal Immigration and Customs Enforcement agents at the checkpoint in Las Cruces often take the cannabis and never return it.

If Scepter Lab shuts down entirely or shuts down partially, producers will have to rely on the laboratory in Las Cruces, and that will result in a high likelihood of federal agents taking the cannabis, thus preventing a test and disrupting the entire supply chain. Relying on the Las Cruces laboratory works well for producers who grow their plants south of the checkpoint at Las Cruces, but producers growing in central or northern New Mexico cannot rely on sending samples to Las Cruces knowing that they may be taken by federal agents.

Furthermore, DOH's new proposed regulations set much more stringent standards for many items than are currently in place. Ultra Health and the other producers do not even know if the laboratories are capable of testing to this level of specificity. Testing to these standards may require new and expensive equipment, with the result that no producer can pass the tests because no laboratory can do the test.

Additionally, it is not apparent that the existing laboratories can handle the volume of testing that will be required once plant counts increase. As DOH knows, the plant limitation has recently been raised from 450 to 1,750. Now, at 450 plants, Ultra Health was doing 400 batch

sample tests per month. Ultra Health estimates it will be doing 2,000-3,000 tests per month at 1,750 plants.

Now, NMAC 7.34.4.10(A) does provide that DOH may waive testing if laboratories are not able to perform the tests. However, mere ability should not be the only factor in waiving testing requirements. A laboratory may have the *ability*, but the test may 1) take so long; or 2) cost so much, that the result is delayed product or product too expensive for patients. DOH, in focusing on laboratories' ability, ignores a holistic view of the market. What good is a product subject to the most rigorous tests if it ends up being too expensive for patients and takes too long to obtain? DOH states its purpose in implementing these rules is to ensure "beneficial use," as is the purpose of the Compassionate Use Act. A product that is too expensive or takes too long to get is not "beneficial."

DOH Does Not Know if Producers Will Be Able to Meet the Standards

Another glaring problem with NMAC 7.34.4.10 is that DOH has no idea if most producers will be able to meet the requirements at a reasonable rate. DOH of course must have testing requirements, but it must balance stringency of testing requirements with overall health of the market. If 95% of products fail the most stringent of testing requirements, is that acceptable to DOH and to patients? If 10% of products fail, is that acceptable?

DOH should adopt a pilot program to test the test—to find out if these are workable standards. Indeed, the standards proposed by DOH are as strict or stricter than those of many other states, including states that have had robust and well-supported programs for much longer than New Mexico has. See, for example, the testing requirements of California and Colorado, attached here.

Incidentally, stricter testing standards in Colorado and California have had negative effects on those states' legal programs, as higher testing expenses are passed on to the consumer and consumers go to the black market instead of staying within the legal market. DOH should look to the negative experiences of these states and ask if lowering a standard by a few parts per million is worth sick patients going to the illegal market to obtain cannabis.

A pilot program, under which the stricter testing is done but the current testing is enforced, would be useful in demonstrating to DOH if the stricter testing mode is necessary or achievable. The pilot program could also provide an indicator on how testing influences black market infiltration—will consumers pay the extra price and wait longer for legal products, or will they return to the black market?

DOH Has Failed to Consult the Medical Advisory Board

Now, Ultra Health itself does have a very rigorous quality control program that influences production practices from seed to sale, and Ultra Health believes very strongly in placing patients' safety above all else. However, it does not seem that DOH has actually consulted the Medical Advisory Board about the proposed testing standards in order to determine if they truly improve patient health.

The Medical Advisory Board is created by statute, NMSA 1978 § 26-2B-6 (2019). The statute creating the Medical Advisory Board does not explicitly say DOH must consult it regarding testing requirements, but given the Board's existence, it would seem strange *not to consult* it on these testing standards. The Board exists to provide professional advice to DOH on the management of the Medical Cannabis Program, and testing standards is right up the Board's proverbial alley.

Indeed, it seems arbitrary, capricious, and absurd for DOH to promulgate rules on safety standards for medical cannabis without consulting the Medical Advisory Board. The Board should have been consulted to determine 1) if the current supply of medical cannabis from licensed entities is not safe enough; 2) if legal sources of medical cannabis were sickening patients at unacceptable rates; 3) if more stringent testing standards would improve safety; 4) if the testing standards were properly balanced against other negative effects, such as increased price and decreased supply.

The failure of DOH to obtain the advice of the Medical Advisory Board regarding testing standards indicates DOH's promulgated standards are arbitrary, capricious, and simply plucked from the air, rather than being the product of scientific consensus.

More Stringent Standards Will Decrease Supply

It also appears DOH has failed to consider how more stringent testing will impact supply. First, there is the impact of the sampling size. The new rules require batch testing and require "off-the-shelf" testing (see 7.34.4.10(C)(6), "Random testing of finished cannabis derived products). Ultra Health calculates that all testing combined will consume one half-pound of every five-pound batch. And of course, the testing called for by DOH is, by its nature, destructive testing—the test destroys the cannabis.

This means 10% of harvested cannabis will be consumed by testing alone. In turn, this means 10% of supply goes to testing rather to patients. If DOH truly wishes to require that much testing, it must adjust the plant count to make up for the material lost to testing.

Additionally, more stringent standards will lead to higher failure rates, and higher failure rates will mean more cannabis is destroyed than goes to patients. Cannabis that does not pass tests and cannot be remediated will be destroyed. The more cannabis destroyed is more cannabis that cannot serve patients.

In this way, more stringent standards drive down supply. If DOH wishes to tighten testing standards, it must know that this will negatively affect supply. The loss to testing failure must be made up with an increase to the plant count.

When DOH calculated patient demand in the spring of 2019, it did so without calculating the amounts lost to failed tests. That is, it calculated the amount of cannabis "sufficient" to meet patient needs in an imaginary, perfect world where no cannabis ever failed tests. However, this

is not a perfect world, and if 25% of cannabis fails tests and is un-saleable, the plant count limitation must be adjusted up by 25% to account for that loss.

This shows, yet again, that managing a medical cannabis market requires balancing different factors. It is highly unlikely that DOH can achieve a working market with both high testing standards and low plant limitations. It would be more likely to achieve a working market with high testing standards and high plant limitations, or lower standards and lower limitations.

To use a popular colloquialism, DOH wants to have its cake and eat it too: it wants to keep plant counts too low to account for plant material lost to failures of stringent testing standards. These testing standards will only result in decreased supply, higher prices, and more patients being driven to the black market.

The Standards Will Result in Producers Closing Their Businesses or Selling Licenses

Ultra Health predicts that instituting uniformly stringent testing standards, without a period for adjustment and without an indication that patient safety is currently compromised, will result in smaller producers closing their businesses or selling licenses to out-of-state interests.

Some producers will simply not have the wherewithal to achieve more stringent standards. The cost of improving their techniques will be very high, and lack of access to capital will prevent them from instituting capital improvements. This will then result in a markedly reduced output or closure of the business entirely. Additionally, current licensees will look to out-of-state interests to buy licenses. This would set a bidding war that does not serve the interests of New Mexico patients.

Currently, both large and small licensed producers face a litany of challenges to the survival of their businesses: 1) the punitively high licensing fees demanded by DOH; 2) punitive tax treatment that results in very large tax burdens; 3) lack of access to capital because of restrictive federal laws; 4) constant competition from the black market; 5) high costs of production because of high energy and water costs. On top of this, DOH adds stringent testing standards that could result in failure rates as high as 95%. In this antagonistic atmosphere, producers could simply start closing.

NMAC 7.34.4.10(E)(5)

NMAC 7.34.4.10(E)(5) provides, "repeated failure to pass testing may result in the imposition of disciplinary action(s) by the department, consistent with this rule."

DOH does not give any indication of what it considers to be "repeated." As stated above, Ultra Health plans to conduct 2,000 to 3,000 tests per month. Of course, there will be repeated failures given this high number of tests. This begs the question of whether two failures will subject a producer to disciplinary action, and certainly, every single producer will have more than two failures.

The producers and manufacturers need to know what DOH considers to be an unacceptable number or percentage of testing failures. When coming to those numbers, DOH should consider that the medical cannabis industry is different in important ways from pharmaceutical manufacturing or food manufacturing. Pharmaceutical manufacturing deals with often inert chemicals, but cannabis producers must deal with a living plant that has all the complexities of a living being.

The variability and failure rate of, say, bread will naturally be different from the failure rate of, say, Coca-Cola, given that bread is made with living microbes (yeast) and Coca-Cola is made from inert sugar. Likewise, the variability and failure rate of cannabis products will be higher than other medicinal products because of the simple fact that cannabis plants are living beings that respond to their environments.

Ultra Health asks that DOH consult with the Medical Advisory Board to come forth with proposals for unacceptable rates of testing failures, with special attention paid to the context of medical cannabis cultivation.

Conclusion

The institution of more rigorous and stringent testing standards and protocols obviously derives from good intentions, but the new rules will result in more negative than positive consequences to the Medical Cannabis Program as a whole.

NMAC 7.34.4.14; Manufacturing Provisions

NMAC 7.34.4.14(B)(3) requires submission of a "hazard analysis critical control point plan" for each type of product manufactured. Again, it appears DOH has derived this requirement from food manufacturing regulations. HACCPs are in fact heavily regulated by the federal FDA, such that the FDA has an extensive article on HACCP guidelines on its website: https://www.fda.gov/food/hazard-analysis-critical-control-point-haccp/haccp-principles-application-guidelines

A recent study by the food industry found that developing a HACCP costs around $25,000 per product for "small establishments." See https://foodindustryexecutive.com/2017/02/how-much-food-safety-compliance-really-costs-for-meat-and-poultry-report/, also attached here.

Now, even if a manufacturer can afford to develop a HACCP plan, it is not apparent what expertise DOH has to judge it. That is, does DOH have employees with expertise in HACCP plans to know if a manufacturer has submitted a genuine one or simply a garbled collection of nonsense.

This is the difficulty in DOH attempting to regulate a subject matter more traditionally regulated by, say, the Department of Environment, or Regulation & Licensing. If DOH is to demand a HACCP, manufacturers must be assured that those plans will be evaluated by

regulators with expertise in the area, and not by inexperienced DOH officials with no real training in food safety.

Again, DOH must balance the 1) perceived need for HACCPs; 2) the actual need for HACCPs; and 3) the burden on manufacturers. Some manufacturers will simply forgo HACCPs and stop manufacturing a particular product. Others may invest in HACCPs but will pass the cost onto patients, resulting in higher prices and flight to the black market.

The recent "vaping crisis" has resulted in increased focus on the safety of tobacco and cannabis products. However, the nexus between HACCPs and the vaping crisis is not apparent. After all, the culprit in serious "vaping" illnesses has been found to be Vitamin E acetate, and DOH's proposed regulations altogether ban the use of Vitamin E acetate.

This shows that DOH can create targeted regulations that reach specific dangers without having to place vague and expensive regulatory burdens on businesses. The specific prohibition on Vitamin E acetate is a reasonable, targeted mechanism designed to specifically reduce one very specific harm at almost no cost to manufacturers. On the other hand, demanding HACCPs is a very onerous burden whose broad reach is not designed to target a specific problem.

Furthermore, the recent "vaping crisis" has proven once again the danger of illicit and illegal sources of cannabis. DOH can most immediately protect the health of New Mexicans by encouraging use of legal sources of cannabis and discouraging illegal sources. Forcing legal manufacturers to raise prices will only discourage legal access and encourage illegal sales.

Again, Ultra Health must ask if the Medical Advisory Board recommended HACCPs or sees a need for them. Ultra Health does not know if DOH has been inundated by patient complaints recently, but if DOH has, it should inform producers and manufacturers so that businesses can make targeted improvements. A HACCP requirement, without evidence of a broad spectrum of patient complaints, is like using a bulldozer to kill a mosquito. Rather, DOH and manufacturers should work together to find specific solutions to specific problems.

NMAC 7.34.4.14(C) Conflates "Additive" and "Addictive"

NMAC 7.34.4.14(C) is titled "prohibited additives" and then states manufacturers shall not "combine nicotine, caffeine, or any other addictive substance" with cannabis. This seems to conflate "additive" with "addictive."

The word "addictive" is not useful if it is not defined. First and foremost, sugar is now considered an addictive substance by many medical professionals. Read broadly, this rule would prohibit the combination of sugar with cannabis, and would therefore ban such products as cannabis gummies, cannabis hard candies, cannabis cookies, cannabis brownies, cannabis lollipops, etc. Prohibiting the use of sugar would decimate the market for edible products.

Ultra Health agrees that certain substances should not be combined with cannabis, but it asks for a specific list given that "addictive" could very well apply to sugar.

NMAC 7.34.4.27; Reciprocity

Ultra Health notes several ambiguities in the provisions regarding reciprocal participation and requests DOH clarify these points so that the reciprocal program may be implemented smoothly.

The rule requires participants to "register with a licensed non-profit producer." Ultra Health assumes this means out-of-state visitors can register with multiple producers and is not restricted to one.

Ultra Health also assumes that this "registration" will be visible to all producers, because all producers must be able to see a person's purchase history in order to ensure that the person does not purchase greater than 230 units within a 90-day period.

Conclusion

Ultra Health requests the Department review these comments in the context of improving the overall health of the Medical Cannabis Program to ensure its long-term success.

Kylie Safa
New Mexico Top Organics-Ultra Health, Inc. Chairperson

SUBMITTED: November 18, 2019

[EXT] Comment from Patient

[redacted]

Wed 11/20/2019 5:37 PM

To:comment, MCP, DOH <MCP.Comment@state.nm.us>;

To whom it may concern-

My name is [redacted] and I've been a patient since 2013. I've seen changes to the program for the better but, the new proposed changes requiring further testing by LNPP's seems unnecessary. It is my understanding these new changes would ultimately affect the patient's wallet. When new costs arise for LNPP's the buck gets passed to the patient too often. New packaging and additional testing do seem like a great idea for the future but, as of now, the program would see a massive shortage of approved flowers as well as a steady rise in price for updated white labels. At the time, this is not what patients need nor want. Regardless, I thank you for reading this and taking my comments into consideration.

Best regards

[redacted]

[EXT] MCP Comment

Taylor Trodden <ttrodden@verdesfoundation.org>

Thu 11/21/2019 12:57 PM

To: comment, MCP, DOH <MCP.Comment@state.nm.us>;

To whom it may concern:

The Verdes Foundation wishes to express concern over the suggested label, and information sheet provided in this Repeal & Replace (https://protect-us.mimecast.com/s/ZMQlCYEnLkiLVAJpH05aaw?domain=7.34.4.16). Table 8's sample label would create logistic issues given the limited size of packaging and container options that exist in the industry. We'd like to suggest that label requirements remain unchanged and that the department allow for the information sheet to be supplied at time of purchase by attaching to the patient's bag. Similar to how information is provided with prescriptions at a pharmacy. The information sheet can be created by each LNPP through BioTrack and would support continuity and uniform presentation between LNPP's.

Taylor Trodden | Compliance Manager | The Verdes Foundation | o.505.280.2814

[EXT] Comments on Proposed Rules NMAC 7.34.4 - Public Hearing Nov. 22, 2019

Kylie Safa <kylie@ultrahealth.com>

Mon 11/18/2019 11:56 AM

To: comment, MCP, DOH <MCP.Comment@state.nm.us>; Sundberg, Andrea, DOH <Andrea.Sundberg@state.nm.us>; Zurlo, Dominick, DOH <Dominick.Zurlo@state.nm.us>;

Cc: Duke Rodriguez <duke@ultrahealth.com>; Marissa Novel <marissa@ultrahealth.com>; Robert Romero <robert@ultrahealth.com>; Leigh Jenke <leigh@ultrahealth.com>; Kristina Caffrey <kristina@egolflaw.com>;

1 attachment

Ultra Health Rulemaking Comments Nov 22 2019 Hearing.pdf;

Attached are Ultra Health's written comments for the public hearing scheduled on November 22, 2019 regarding proposed rules NMAC 7.34.4.

Please confirm receipt of this email.

--

Kylie Safa
Chief Operating Officer

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[EXT] Comments on Proposed Medical Cannabis Testing Rules

Amber Lengacher <amber@vicentesederberg.com>

Thu 11/21/2019 4:27 PM

To:comment, MCP, DOH <MCP.Comment@state.nm.us>;

1 attachment

New Mexico Proposed Medical Cannabis Testing Rules Comment Submission.pdf;

Ms. Sundberg or Other Department of Health Representative,

Good evening, hope this finds you well.
Please see the attached comment submission in regards to the Proposed Repeal and Replacement of 7.34.4, scheduled for public hearing tomorrow, November 22, 2019.
If you have any questions about this document or the comments contained therein, please feel free to reach out to me directly.

Thank you for your time and attention to this matter.

Amber D. Lengacher
Associate Attorney

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November 21, 2019

DELIVERED VIA EMAIL TO: MCP.comment@state.nm.us
Andrea Sundberg
New Mexico Department of Health
Medical Cannabis Program
P.O. Box 26110
Santa Fe, New Mexico, 87502-6110

Re: New Mexico Proposed Medical Cannabis Testing Rules Comment Submission

Dear Ms. Sundberg:

Thank you for taking the time to read these suggested comments regarding the Proposed Repeal and Replacement of Rule 7.34.4 (the "**Proposed Rules**"), published on the New Mexico Department of Health's Medical Cannabis Program ("**Department**") website. We are extremely grateful to the Department for the release of rules governing the Testing of Usable Cannabis and for the time the Department has taken to establish this program. With that in mind, we respectfully suggest the following changes to the Proposed Rules:

Definition of "Batch" – Section 7.34.4.7(H)
We suggest amending the definition of "batch" as it is used in section 7.34.4.7(H) to remove the word "homogenous." Raw usable cannabis flower will never be homogenous because it is an unprocessed organic substance. Instead, the definition should clarify that usable cannabis can be considered within the same batch if it is harvested in the same period, of the same strain, and used in the same agricultural practices and inputs.

> "'Batch' means, with regard to usable cannabis, an [homogenous,] identified quantity of cannabis no greater than five pounds that is uniform in strain, cultivated with the same agricultural chemicals, and harvested during a specified time period from a specified cultivation area, and with regard to concentrated and cannabis-derived product, means an identified quantity that is uniform, that is intended to meet specifications for identity, strength, and composition, and that is manufactured, packaged, and labeled during a specified time period according to a single manufacturing, packaging, and labeling protocol."

Sampling Procedures – Various Provisions Detailed Below
Section 7.34.4.8(F)
First, we suggest removing the provision in Section 7.34.4.8(F) that would allow a non-profit producer to contract with a medical cannabis courier for the sampling and transportation of usable cannabis to a testing laboratory. Instead, the Department should implement a program by which *the testing laboratories themselves* select and transport samples for testing directly. This program will ensure the reliability, impartiality, and accuracy of medical cannabis testing by preventing

individuals who may have ulterior motives or other interests in cannabis products from sampling and transporting medical cannabis, which could result in the manipulation of testing results. Independent, incentivized, third-party medical cannabis testing by nature must include the direct sampling and secure transportation of cannabis samples by independent, trained, and supervised laboratory personnel. This would also allow testing labs to retain more control over the samples, further safeguarding against possible sample contamination or compromise from companies unknown to the testing lab.

> "Production and distribution of medical cannabis by a licensed non-profit producer to a qualified patient or primary caregiver shall take place at locations described in the non-profit producer's production and distribution plan approved by the department, and shall not take place at locations that are within 300 feet of any school, church, or daycare center. For purposes of this provision, delivery to the residence of a qualified patient or primary caregiver shall not be deemed "distribution". A licensed non-profit producer may, consistent with this rule, and with the consent of a purchasing qualified patient or primary caregiver, utilize an approved courier to transport usable cannabis to a qualified patient or primary caregiver, and may for this purpose share with an approved courier the contact information of the purchasing qualified patient or primary caregiver. A licensed non-profit producer may, consistent with this rule, also utilize an approved courier to transport usable cannabis to another non-profit producer~~, to an approved laboratory,~~ and to an approved manufacturer. A licensed non-profit producer shall not identify any person as an intended recipient of usable cannabis who is not a qualified patient, a primary caregiver, an approved courier, an approved manufacturer, or an approved laboratory."

Section 7.34.4.10

Second, we recommend the Department consider changing the responsibility for product sampling in section 7.34.4.10 from the licensed non-profit producer or manufacturer to an approved laboratory. We believe giving licensed non-profit producers or manufacturers the ability to sample products for testing represents a potential conflict of interest that could result in the selection of non-representative samples.

> "All dried usable cannabis produced by a non-profit producer, and all concentrated cannabis derived products manufactured by a non-profit producer or manufacturer, shall be sampled ~~for testing purposes by the licensed non-profit producer or manufacturer,~~ and ~~those samples shall be~~ tested by an approved laboratory consistent with the requirements of this rule and found to have passed all tests required by this rule, prior to the sale, distribution, or other use of the product. Each batch of dried usable cannabis shall be segregated and sampled by ~~the non-profit producer that produced the batch~~ an approved laboratory, and the non-profit producer shall ensure that each sample is tested by an approved laboratory in accordance with the testing requirements of this rule and determined to have passed the following individual testing requirements, before dried usable cannabis from that batch is made available for sale or distribution, and before the dried usable cannabis or any substance derived therefrom is incorporated into a cannabis derived

product. Each batch of concentrated cannabis derived product shall be segregated and sampled by ~~the manufacturer or non-profit producer that produced the batch~~ an approved laboratory, and the manufacturer or non-profit producer (as applicable) shall ensure that each sample is tested by an approved laboratory in accordance with the testing requirements of this rule, and determined by the manufacturer or non-profit producer (as applicable) to have passed the following individual testing requirements, before cannabis derived product from that batch is made available for sale or distribution."

Section 7.34.4.10(E)
Third, we recommend a similar change to the following subsection:

"Procedures for testing: A licensed non-profit producer and a manufacturer shall ensure that the following testing procedures are followed:

(1) sampling and segregation: ~~a licensed non-profit producer or manufacturer~~ an approved laboratory shall remove a sample of no less than the quantities of cannabis or cannabis derived product specified in Table 7, Minimum Test Sample Size, from every batch, and ~~shall transfer the~~ transport the sample to ~~an~~ the approved laboratory's facility for testing; the remainder of the batch of dried, usable cannabis or concentrated cannabis-derived product shall be segregated until the licensed non-profit producer receives the results of laboratory testing report and determines whether the batch meets the testing requirements of this rule;"

Sample Size – Section 7.34.4.10(E)(1)(7)
We respectfully suggest reducing the minimum test sample size in Section 7.34.4.10(E)(1)(7) for Total Aerobic Microbial Count testing from ten grams down to one gram. The minimum sample size for the Total Aerobic Microbial Count testing (10g) appears to be quite large given the colony-forming test units (cfu) established in Section 7.34.4.10(C)[1]. The sample size for testing indicated in the internationally recognized standard, AOAC 997.02, is based on the corresponding cfu. If the cfu is one gram, then the sample size should be one gram as well. For cfu/10g, a sample size should be 10g. Section 7.34.4.10(C) establishes units of cfu/g or cfu/mL for the Total Aerobic Microbial Counts testing of various final products for various analytes. Therefore, the sample size should correspond and be one gram, not ten.

"Total Aerobic Microbial Count	dried usable cannabis, concentrate, or cannabis -	Direct culture, indirect culture, or non-culture	1~~0~~.0"

[1] AOAC Method 997.02 Yeast Count and Mold Count

Remediation and Subsequent Testing - Section 7.34.4.10(F)

We respectfully suggest amending section 7.34.4.10(F) to include testing for heavy metals and pesticides during the post remediation re-resting phase for contaminated products that have undergone processing and extraction to remediate the product.

> "If a sample fails a given test (i.e., if the sample does not measure below the action levels specified in this rule), the non-profit producer or manufacturer (as applicable) shall determine whether remediation is appropriate, and may pursue confirmatory testing at another approved laboratory. In the event that a non-profit producer or manufacturer attempts to remediate cannabis or a cannabis derived product, the batch shall again be sampled and subjected to all of the tests identified in this rule, except those required for heavy metals and pesticides. Remediated products must be retested by an approved laboratory for all required analytes, including but not limited to heavy metals and pesticides. A batch of usable cannabis that fails a given test and that does not pass the required tests subsequent to remediation conducted in accordance with the terms of this rule, shall be destroyed in accordance with the wastage requirements of this rule. A non-profit producer or manufacturer may remediate cannabis or cannabis derived product in accordance with the following:"

Units of Measurement – Section 7.34.10(C)

We respectfully suggest a change to fix an error in the Proposed Rules in section 7.34.4.10(C), which incorrectly presents the units of measurement throughout the tables for action levels. For instance, the action levels for mycotoxins are in milligrams per kilogram (mg/kg) or parts per million (ppm) however the measurement descriptor refers to micrograms per kilogram (µg/kg) or parts per billion (ppb). This same issue occurs in other tables that present measurements in milligrams (mg) but refer to micrograms (µg). This should be changed in this section and throughout the regulations to codify the correct unit of measurement and provide clarity to approved laboratories.

We would also suggest amending several parts of section 7.34.4.10(C)(1-3) regarding the action levels for various required testing to ensure they are appropriate, as noted below.

For microbial testing, we have observed that the action limit on cfus of combined yeast and mold are orders of magnitude lower than the action limits currently used in the State of Colorado and internationally recognized organizations[2] [3]. Additionally, we noted that most of the established limits align with USP 2023 for final products except for Nutritional Supplements with Botanicals. We suggest that lower action limits be adopted for the Total Aerobic Microbial Count parameter[4].

For mycotoxin testing, we have observed the action levels are described in parts per billion (**ppb**), and they are equivalent to the limits prescribed in Colorado. Therefore, we suggest that both Method Reporting Levels and Action Levels be measured in micrograms per kilograms (µg/kg).

[2] AOAC Method 997.02 Yeast Count and Mold Count
[3] FDA Bacteriological Analytical Manual Chapter 18
[4] USP 2023 recommends Total Aerobic Microbial Count NMT 10^4 cfu/g

For solvent testing, we have observed that the permitted parts per million (**ppm**) of residual solvent are lower than the limits established in Colorado for similar solvents extraction. But the permissible threshold for some dangerous non-permitted solvents, typically found as a minute byproduct in extraction gases, are higher than what is established in Colorado and USP standards.[5] Therefore, we suggest mirroring the solvent residual limits established in Colorado, which has engaged its Department of Public Health over multiple years to determine the most appropriate levels.

For heavy metals testing of inhaled cannabis flower, we suggest amending section 7.34.4.10(C)(5), considering that the limit on acceptable ppm for inhaled cannabis flower are higher than the limits in Colorado for all heavy metals except for mercury. Colorado also has different heavy metal allowances for inhaled, topical or orally consumed products. We suggest that both Method Reporting Levels and Action Levels be measured in micrograms per grams (µg/g).

For pesticide testing, we suggest amending both Method Reporting Levels and Action Levels to be measured in micrograms per kilograms (µg/kg) for section 7.34.4.10(C)(6).

Random Testing of Finished Cannabis Derived Products – Sections 7.34.4.10(C)(8)

We suggest revising section 7.34.4.10(C)(8) to replace the requirement that non-profit producers or manufacturers conduct random testing with the requirement that random sampling for quality control auditing should be performed by the state's Department of Health to ensure that non-profit producers or manufacturers do not avoid sampling batches with suspected or potential contamination. Additionally, the Department of Health's randomized testing standards are already codified in Section 7.34.4.12.

> "~~A non-profit producer or manufacturer that manufactures~~ The Department, or a contracted independent testing laboratory, ~~a cannabis derived product~~ shall establish a schedule for, and shall conduct, random sampling and testing of finished, non-concentrated cannabis derived products, including but not limited to edible cannabis derived products, as follows:
>
> > (a) The ~~non-profit producer or manufacturer~~ Department, or a contracted independent testing laboratory, shall randomly select and sample at and at least one percent of all non-concentrated cannabis derived product batches manufactured every week (and no less than one batch);
> >
> > (b) The ~~non-profit producer or manufacturer~~ Department, or a contracted independent testing laboratory, shall apply the sampling and testing standards that otherwise apply under this rule to dried cannabis and concentrated cannabis derived products; and
> >
> > (c) In the event that a sample fails any of the required testing, the non-profit producer or manufacturer ~~batch~~ shall not allow the batch

[5] USP 467, EPA 310B

> to be sold, distributed, or otherwise used, unless remediated in accordance with the remediation standards of this rule."

Potency Testing – Section 7.34.4.10(C)(4)(a)

We recommend the Department amend section 7.34.4.10(C)(4)(a) to include potency testing best practices from Colorado and other states in accordance with the following:

> "Homogeneity in potency: A cannabis derived product shall be homogenous in composition with respect to THC potency. A cannabis derived product shall not be considered homogenous if 10% of the infused portion of the cannabis derived product contains more than 20% of the total THC contained within the entire cannabis derived product. In the event that a cannabis derived product does not meet this requirement, the batch shall be destroyed."

Ownership Disclosures – Section 7.34.4.14(C)(7) & (8)

We further recommend reconsidering the disclosures required in sections 7.34.4.17(C)(7) & (8) to only require disclosure for individuals who hold over a specific percentage of ownership (i.e. greater than 10-20%[6]) or who would otherwise exercise **directional control** over the license. Otherwise, an approved cannabis laboratory may be unable to receive the required capital contributions to successfully operate or obtain access to certain funding streams from investors with a large number of shareholders.

Disposal of Cannabis Waste – Section 7.34.4.18(O)

We respectfully suggest removing portions of section 7.34.4.18(O), specifically the section which references the optional transport of cannabis waste from an approved laboratory to a state or local law enforcement office. Disposal is already governed by sections 7.34.1.11 and 7.34.4.18(D) and adding the additional optional language here could confuse laboratory operators and potentially result in non-compliance.

> "Unused cannabis, cannabis products, or cannabis-derived product waste that is in the possession of an approved laboratory shall be ~~disposed of by transporting the unused portion to a state or local law enforcement office, or by destruction of the material~~ destroyed and disposed of in accordance with sections 7.34.1.11 and 7.34.4.18(D)."

We appreciate your consideration of this commentary and its references to existing cannabis programs. Thank you again for your time and attention to this matter.

[6] CCR Title 16 Div. 42 Bureau of Cannabis Control § 5003(5). Designation of Owner – California

[EXT] Written Comment proposed rulerevisions

[redacted]

Thu 11/21/2019 5:25 PM

To: comment, MCP, DOH <MCP.Comment@state.nm.us>;

Good Afternoon,

I am concerned that the proposal for extensive testing will create a downward spiral for patients and producers, alike, and would like to present some feasible solutions. The main concern is the impending costs for the testing which will ultimatey be incurred by patients in the MCP. The ecomomic situation in New Mexico simply cannot support continually rising costs for a medicine that is not covered by insurance. New Mexico is the second leading state in Medicaid enrollments at 732,432 residents out of 2M residents. This is a strong indicator that medical costs are simply unaffordable to a considerable amount of the populace.

One of the main goals of producers is to ease the financial burden of out-of-pocket costs for patients in the program. Increasing testing requirements when no underlying issues currently exist is unwarranted. Potential problems could arise for both patients and producers including but not limited to:

- smaller producers not being able to afford the the increased testing costs
- a longer waiting period to complete testing and a backlog overloading the only two testing labs in NM making producers unable to fill the LECUA requirements of a 90 day unlimited supply of cannabis medication
- Increased costs, ultimately incurred by patients, alleviated through increasing product prices
- Increased costs of what is (under current testing conditions) safe, tested cannabis driving patients to the illicit cannabis market creating a health safety issue

The following are possible solutions to temper these potential problems.

Pertaining to pesticide testing, NMDOH can produce a list of banned substances such as caustic substances and certain pesticides. To prevent producers from circumventing these substances NMDOH can require random sampling tests on whatever products they choose and if any of the banned substances are found, a substantial sanction should be imposed. This quells the costs of testing every batch for hypothetical problems.

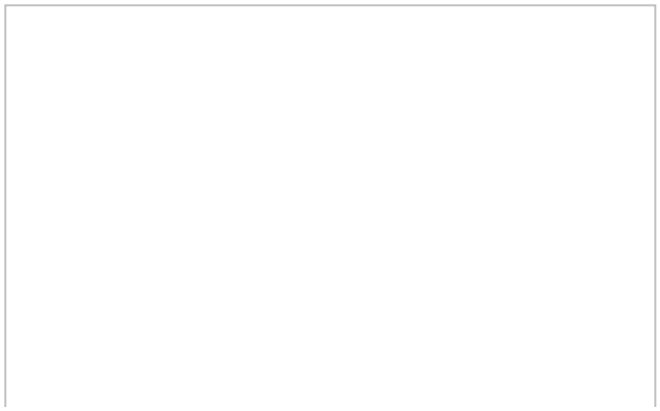
Another plausible solution is to impose price caps on labs for the state required testing. This will prevent the costs of extensive testing from doubling back on patients which could induce them to seek untested, unregulated and unsafe medicine from the ever present and increasing black market.

[EXT] Medical Cannabis Program Nov 22nd 2019 Proposed Rule Hearing Public Comment

Jason Barker <safeaccessnewmexico@gmail.com>

Fri 11/22/2019 4:24 AM

To: comment, MCP, DOH <MCP.Comment@state.nm.us>;



Safe Access New Mexico

Jason Barker
[redacted]
SafeAccessNewMexico@gmail.com

Friday, November 22nd 2019

Andrea Sundberg
NM Department of Health
Medical Cannabis Program
P.O. Box 26110
Santa Fe, NM 87502-6110

MCP.comment@state.nm.us

Safe Access New Mexico would like to thank the Department of Health for taking these public comments for review with the Proposed Rule Hearing.

This statement on the Dept. of Health proposed MCP Vape Warning label is completely false and even worse it misleads the general public and program participants about the scientific facts about THC and it's many medical benefits.

"WARNING: Vaping THC has been associated with cases of severe lung injury, leading to difficulty breathing, hospitalization, and even death"

I would please like to ask the Department of Health to reconsider the current language now being used as a "warning label" for medical cannabis vaping products. The warning label is very misleading and to clear that up, I would suggest adding the following factual statement to the Warning Label: ***"It is important to note that this illness is not caused by anything intrinsic to cannabis. "***

Update 11/8/2019: The CDC has confirmed that out of 29 samples of lung fluid from affected patients all samples tested positive for Vitamin E acetate. This has led the CDC to consider Vitamin E acetate to be a "chemical of concern." Not solely THC.
Source: Patient-Focused Recommendations Regarding the Vaping Crisis | https://www.safeaccessnow.org/patient_focused_recommendations_regarding_the_vaping_crisis

The Centers for Disease Control and Prevention issued vaping guidance noting that "products containing THC, particularly those obtained off the street or from other informal sources…are linked to most of the cases and play a major role in the outbreak" and recommending that… "persons consider refraining from using e-cigarette, or vaping, products that contain nicotine."

New Mexico unfairly singled out medical cannabis vape products to include a health warning, despite facts from CDC.
[https://nmhealth.org/about/asd/cmo/rules/]

Why has the state singled out products in the New Mexico medical cannabis program for 'warning labels' amidst the Outbreak of Lung Injury Associated with E-Cigarette Use, or Vaping, known as Vaping-Associated Pulmonary Illness (VAPI)?

Medical cannabis manufacturers and producers must label their THC-containing vape products with: *"WARNING: Vaping cannabis-derived products containing THC has been associated with cases of severe lung injury, leading to difficulty breathing, hospitalization and even death,"* MJ Business Daily reported.
And the statement made on these warning labels are not entirely accurate based on CDC Data for VAPI.
[Link to all that CBD data: https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease/resources/index.html]

The New Mexico Health Department did not require any "Warning labels" on nicotine vaping products.
The New Mexico Environment Department has not required any "Warning labels" on any Hemp CBD vaping products.

The state of New Mexico has singled out only THC medical cannabis vaping products and ignored the true problems causing the Outbreak of Lung Injury Associated with E-Cigarette Use, or Vaping. Nor has the NM Department of Health posted anything about this "warning label" to the state's medical cannabis program website to inform the medical cannabis program participants, as of Friday morning October 11 2019.

[Link: https://nmhealth.org/about/mcp/svcs/]

Problems the CDC has found, that state has failed to mention such as adulterants, contaminants, heavy metals, residual solvents, chemical residues, and other health concerns, such as mold and dangerous bacteria.

It is important to note that this illness is not caused by anything intrinsic to cannabis and the state of New Mexico has failed to mention that key fact.

The state should be encouraging participation in the state's medical cannabis program amidst the Outbreak of Lung Injury Associated with E-Cigarette Use, or Vaping instead using scare tactics on a warning label. The focus of the problem for New Mexico should be the blackmarket and those promoting the use of the blackmarket.

The available evidence from the CDC indicates that the vast majority of those who were sickened after using a vaporizer cartridge purported to contain THC purchased their cartridges not through legally licensed stores, but through unregulated, illicit channels. Additionally, CDC data indicates that 16% reported the exclusive use of nicotine-containing products in the 30 days prior to symptom onset.
But no "warning label" for those nicotine vape products in New Mexico.

Some operators are cashing in on the Hemp CBD craze by substituting cheap and illegal synthetic marijuana for natural Hemp CBD in vapes and CDC data shows this has caused Vaping-Associated Pulmonary Illness (VAPI).

The AP News commissioned laboratory testing of 29 vape products sold as Hemp CBD around the country, with a focus on brands that authorities or users flagged as suspect. Ten of the 30 contained types of synthetic marijuana — drugs commonly known as K2 or spice that have no known medical benefits — while others had no CBD at all.
And we have seen two Albuquerque news stations expose some Hemp CBD retail stores for selling questionable/mislabeled products, but no "warning label" for those Hemp CBD vape products in New Mexico.
[KOAT News Hemp CBD Investigative Story: https://www.koat.com/article/mixed-bag-of-results-whats-really-in-your-cbd-products/27532208
KOB News Hemp CBD Investigative Story: https://www.kob.com/new-mexico-news/4-investigates-cbd-industry-is-operating-in-the-dark/5359467/?cat=500]

The New Mexico Department of Health also forgot to mention how they decided not to test New Mexico medical cannabis products for Heavy Metals, Pesticides and other dangerous toxins - All of which have been found in vaping products by the CDC that are making people sick.
Steep Hill labs warned lawmakers and the Department of Health about this in October 2017 at a Legislative Health and Human Services Committee Meeting and the state did nothing.
[Link to those Steep Hill Handouts:
https://www.nmlegis.gov/handouts/LHHS%20101617%20Item%209%20Dr.%20Reggie%20Gaudino%20Testimony%20with%20NM%20Samples%2010_17_17.pdf]

A California based cannabis testing lab, CannaSafe, found that out of 12 illicit cannabis vape cartridges they tested, nine contained high levels of Vitamin E acetate and ALL contained pesticides, while none of the 104 legal products they examined had those contaminants.
[Link to that testing: https://www.businessinsider.com/study-counterfeit-vapes-contain-vitamin-e-pesticides-and-hydrogen-cyanide-2019-10]

Nor did the Department of Health consult any national organizations that are experts in cannabis policy, medical cannabis regulatory affairs, or in medical cannabis scientific research before issuing this biased health warning.

Americans For Safe Access(ASA) points out that as of yet, CDC investigators have not been able to pin down one factor or set of factors that is likely to result in illness. Vitamin E (tocopherol) acetate has been implicated as a potential cause of illness and injury in many of the cases involving illicit cannabis cartridges, but it has not been present in all samples. CannaSafe, a PFC-certified lab in California, recently revealed results from a small study that showed black market cartridges can contain extremely high concentrations of other dangerous chemicals, such as myclobutanil, a pesticide routinely found in cannabis samples that is converted to the poison hydrogen cyanide when heated to 400 °F (204.4 °C). CannaSafe also tested 10 illicit cartridges for myclobutanil and found it in each one, highlighting the need for patients and consumers to purchase products that have been subjected to mandatory testing for dangerous chemicals and other hazards. Additionally, such cartridges can contaminate their contents with heavy metals like arsenic and lead. However, the recent disclosure that at least one death has been linked to a legally purchased product underscores that this risk is not just confined to the illicit market.

ASA Recommendations

Whether due to better healthcare surveillance and reporting, the addition of new cutting agents or other additives, the presence of pesticides or other contaminants, issues with certain types, brands, or manufacturers of cartridges and other delivery mechanisms, a combination of these factors, or something else, it is clear that the use of ENDS is not without risk. ASA strongly recommends patients and consumers stop using cannabis-containing cartridges entirely (or at least to the extent possible) until there is clarity as to what is causing these illnesses and deaths.
ASA does not support outright bans on cannabis-containing cartridges or devices intended for the consumption of cannabis concentrates, which could simply drive more people to the unregulated market and exacerbate the spread of VAPI. Rather, we recommend bans on the inclusion of any additives (e.g., diluents, thickeners, flavoring agents) not derived from cannabis. Additionally, we recommend patients and consumers only purchase cannabis products that have undergone testing at an independent, third-party laboratory that has verified composition and potency and screened for adulterants, contaminants, heavy metals, residual solvents, chemical residues, and other health concerns, such as mold and dangerous bacteria.

Vape Alternatives

We understand that for many patients, inhalation may be the preferred - or the only effective - method of delivery. Historically, inhaling cannabis vapor has been considered a safer alternative to inhaling cannabis smoke because the toxic byproducts of combustion are avoided. While this is still believed to hold true for dry herb (flower) vaporizers, vape pens, though convenient and easy to use, should be

avoided at this time. ASA recommends that patients and consumers who currently use a vape pen instead use other delivery mechanisms, such as dry herb vaporizers, tinctures, edibles, or topicals. Patients who must be able to medicate discreetly and rely on vape pens because they don't produce cannabis' signature scent may find combining the use of a flower vaporizer and a personal smoke filter to be a workable solution.

Conclusion

Americans for Safe Access started out in 2002 with the mission to not just ensure access to medical cannabis to patients across the county, but to ensure safe access. As a patient-focused organization, we take the safety of patients very seriously, and the emergence of VAPI has caused us great concern. The current health crisis that is being linked to the use of illicit concentrate vaporization products highlights the importance of legalization, regulation, laboratory testing of all cannabis and cannabis-derived products (most critically when they are in their final form), and third-party certification, such as that offered through ASA's Patient Focused Certification (PFC) program.

Since 2014, ASA has urged the industry to adopt third-party certification for all cannabis businesses. Through the PFC program, companies are required to adhere to safety, quality, manufacturing, testing, packaging, and labeling standards beyond those set by most jurisdictions where the medical and/or adult use of cannabis has been legalized.

PFC companies are subject to both routine and unannounced inspections by independent auditors, which is especially important in light of the fact that jurisdictions may not have enough inspectors to ensure that all licensed operators are complying with all regulations. Patients and consumers may wish to encourage the dispensaries they patronize and the brands that produce the products they use to explore PFC certification to ensure patient and consumer safety and product quality. ASA will continue to do our part for patients, who are and always will be our highest priority, by keeping up the pressure on industry to adopt regulations that promote patient and consumer safety and by persisting in our advocacy for safe access to cannabis for patients everywhere.

Use these resources to learn more about medical cannabis regulations and patient care:

• American Cannabis Nurses Association uses advocacy, collaboration, education, research, and policy development to support cannabis nursing practice.
http://cannabisnurses.org/

• Americans for Safe Access is dedicated to ensuring safe and legal access to cannabis for therapeutic use and research.
https://safeaccess2.org/cannabiscarecertification/
https://www.safeaccessnow.org/pfc_1pager

• Healer is an online support community for patients using medical cannabis.
http://healer.com/

• Project CBD is a nonprofit in California dedicated to promoting and publicizing research into medical cannabidiol use.
http://projectcbd.org/

• Society of Cannabis Clinicians provides continuing education, facilitates best practices, and conducts research related to medical cannabis.
https://www.cannabisclinicians.org/

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Safe Access New Mexico
Jason Barker - Organizer & Medical Cannabis Patient
[redacted]

Americans For Safe Access - Member
American Cannabis Nurses Association - Member
Medical Cannabis Patient in New Mexico

"The American Medical Association has no objection to any reasonable regulation of the medicinal use of cannabis and its preparations and derivatives. It does pretest, however, against being called upon to pay a special tax, to use special order forms in order to procure the drug, to keep special records concerning its professional use and to make special returns to the Treasury Department officials, as a condition precedent to the use of cannabis in the practice of medicine."
~Wm. C. Woodward, Legislative Counsel - 11:37 AM Monday, July 12, 1937

[EXT] Comments in 7.34.4 Repeal and Replace

Jason Marks, Esq. <lawoffice@jasonmarks.com>

Fri 11/22/2019 8:23 AM

To: comment, MCP, DOH <MCP.Comment@state.nm.us>;

1 attachment

JML Comment.pdf;

Please see attached written comments, submitted in response to the Notice of Public Hearing.

Thanks, and best regards,

Jason

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Jason Marks Law, LLC | 1011 Third St NW | Albuquerque, NM 87102 | (505) 385-4435

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November 22, 2019

Ms. Andrea Sundberg
NM Department of Health
Medical Cannabis Program
P.O. Box 26110
Santa Fe, NM 87502-6110 *via email to MCP.comment@state.nm.us*

Comments on Proposed regulations at 7.34.4 NMAC

Dear Ms. Sundberg:

This letter is filed as public comment in response to the Department's Notice of Public Hearing on the repeal and replacement of MCP rules at 7.34.2, 7.34.3, and 7.34.4 NMAC. These comments are based on the knowledge and experience gained through providing legal representation to more than one-quarter of all the entities holding medical cannabis production licenses, or their affiliates, to the largest medical cannabis testing laboratory in New Mexico, and to licensed manufacturers and patients.

Many of the Department's proposed revisions to the MCP rules are required by the 2019 amendments to the Lynn and Erin Compassionate Use Act (LECUA), or are otherwise good policy which continues the development of a program that puts a focus on providing patients with access to safe and effective medicine. Having supported and led state agency rulemakings myself, I understand and appreciate the level of effort by Department staff that went into creating the regulatory revisions that the Department now proposes. I also recognize that, in a welcome departure from past practices, the Department made some effort to consult with industry participants prior to publishing its final proposed rules. However, it appears that the Department did not bring an open mind to these limited consultations, and instead proceeded to publish its initial revisions without regard to feedback received. This is certainly the case as it concerns some of the testing requirements.

My specific comments follow:

1. **The Department May Not Reserve the Power to Promulgate Ad Hoc Rules**

The Department of Health may only promulgate rules affecting the entities it regulates by going through a formal rulemaking process with notice and comment, and publishing such rules in the Register and the Administrative Code. Yet, throughout the proposed 7.34.4 NMAC, the Department has purported to reserve to itself the power to create *ad hoc* regulations at its discretion, without going through notice and comment, or publication. This is not permitted by statute. The defective rules include (the following may not be an exhaustive list):

7.34.4.8(G)(4) "requiring additional information as the department deems necessary"[1]

7.34.4.8(O)(14) "such other policies or procedures as the department may require."

7.34.4.14(B)(25) "such other materials as the department may require."

7.34.4.17(D)(11) "such other materials as the department may require."

7.34.4.22(I)(3) ". . .such other information as the department may reasonably request."

7.34.4.26(B)(12) "such additional information or materials as the department may require."

7.34.4.29(B)(3)(r) "Such additional information as the department may request."

The Department of Health's organic act provides that: "Unless otherwise provided by statute, no rule affecting any person or agency outside the department shall be adopted, amended or repealed without a public hearing on the proposed action before the secretary or a hearing officer designated by him." NMSA 1978 9-7-6(C). "The statutory designation for an enactment by an agency designed to have the force and effect of law and to control the actions of persons who are being regulated by the agency is a 'rule'." *Bokum Res. Corp. v. N.M. Water Quality Control Comm'n*, 1979-NMSC-090, ¶ 41; see also NMSA 1978 14-4-2(C) ("rule" is any regulation or standard purporting to affect persons not employees of a state agency).

In each of the instances listed above, the Department purports to claim the ability to control the conduct of regulated entities using standards that it has not published in a formal regulation. That is improper. While all the examples provided above are defective, the most egregious is 7.34.4.8(O)(14), by which the Department purports to reserve unlimited power to impose new regulations on LNPPs without going through rulemaking. These defective rules should be stricken, and the Department should promulgate regular and emergency rules, as needed, as regulatory concerns change.

2. The Department May Not Restrict Producers to Non-Profit Corporations

The LECUA, as amended by SB 406, authorizes the Department to license "cannabis producers." NMSA § 26-2B-3(G). A cannabis producer is "a person that is licensed by the department to possess, produce, dispense, distribute and manufacture cannabis and cannabis products and sell wholesale or by direct sale to qualified patients and primary caregivers." *Id.* (emphasis added). Elsewhere, the Legislature directed the Department

[1] I recommend that subpart G be replaced with "The department may verify information contained in each application and accompanying documentation by requiring supporting documentation or other reasonable means" and striking the subparts" and striking the numbered subparts. The department obviously needs the ability to verify information, but (G)(4) opens the door to the Department unlawfully changing the application requirements .

to issue licenses to "(1) cannabis couriers; (2) cannabis manufacturers; (3) cannabis producers; (4) cannabis testing facilities; and (5) any other activity or person as deemed necessary by the department." NMSA § 26-2B-6.1(D). The Department mostly complies with this in its proposed regulations by providing for the licensure of "couriers," "manufacturers," and "laboratories," but the Department doesn't license "producers." Instead, the Department has created a category of licensure different from the statute, the "non-profit producer."

The Department, under the authority of Section 26-2B-6.1(D)(5) could create the non-profit producer category, but only as an alternative to a generic "producer," which must be an entity that is a legal "person" of any type. This is required by the Uniform Statute and Rule Construction Act, which provides that the word "person" when used in statute, such as in the LECUA definition of "cannabis producer" *supra*, means "an individual, corporation, business trust, estate, trust, partnership, limited liability company, association, joint venture or any legal or commercial entity." NMSA 1978 § 12-2A-3(E).

In addition to being contrary to the Department's statutory authority, restricting producers to non-profit corporations is arbitrary and unjustified. Operation of a medical cannabis producer compliant with the Department's regulatory standards requires substantial capital investments. Nonprofit entities are unable to obtain capital as equity investments. The bank that has single-handedly made it possible for New Mexico cannabis businesses to have access to depository banking services since 2015 does not issue commercial loans to medical cannabis businesses. The ability of medical cannabis producers to obtain debt financing from private persons and entities who are related parties is very limited, and comes at a high cost.

In response to the Department's *ultra vires* and poorly conceived policy restricting producer licenses to nonprofit entities, for-profit affiliates of LNPPs have proliferated as a means of generating investment capital and incentivizing cost-effective operations. The economic effects of such affiliations are, in many cases, almost the same as if the license was held by a for-profit, but with a loss of transparency and diminished accountability. The Department is well aware of these arrangements, and routinely approves (or passes) on them. The Department's proposed regulations evidence the confusion, referring in places to the "owners" of nonprofit producers. Further, as the Department is aware, LNPPs receive none of the tax benefits of non-profit status.

For the preceding reasons, the Department should eliminate the restriction of producer licenses to non-profits and permit existing license holders to transfer licenses to their existing affiliates.

3. Application of the Three-Hundred Foot Limit Must Comport to Statute

The Legislature prohibited cannabis <u>distribution</u> activities within 300' of a school, church, or daycare center. NMSA § 26-2B-7(A)(6)(b). The Legislature did not extend the 300' requirement to production facilities, or for that matter to laboratories or manufacturers. For production facilities, the Legislature specified instead that they be on

"secured grounds." NMSA § 26-2B-7(A)(6)(a). Under the well known canon that, when the Legislature shows it knows how to enact a provision in one circumstance, but does not do so in another, legislative intent is that the Legislature did not intend that provision to apply where it was not specified.

Moreover, there are obvious reasons why the Legislature could have wanted to put a buffer between school children and preschoolers and the very public activities of retail cannabis distribution. There is no obvious or even plausible reason why production activities, which are not visible to persons outside of the building in which they are housed, would need to be placed a distance from schools and churches. The Department should change 7.34.4.8(F) to only apply the 300' restriction to producers' distribution facilities, to be consistent with statute, and remove it from .9(A) 5, .14(B)(8), .15(A)(5), and .17(C)(18).

Next, the Legislature amended the LECUA in 2019 with SB 406 to address the situation in which a cannabis facility is compliant when it is first opened and approved, but subsequently a school or church moves into the 300' radius, by adding the underlined words:

> distribution of cannabis to qualified patients or their primary caregivers to take place at locations that are designated by the department and that are not within three hundred feet of any school, church or daycare center <u>that were in existence in that location before the licensee distributing medical cannabis nearby was licensed</u>;

The Department must add these underlined words to 7.34.4.8(F). If the Department does not remove the 300' restriction from the production, manufacturing, and laboratory rules to comport with the Legislative intent that the 300' limit only applies to cannabis distribution, it must add the above-underlined words to the respective rules to be in partial compliance with statute.

4. Standards Necessitating License Amendment are Over-Broad

The proposed regulations at 7.34.4.8(R)(2) and .17(J)(1) require application license amendment by a producer or laboratory upon "any physical modification or addition to the facility." This is an arbitrary and over-broad standard bearing no relation to any legitimate regulatory concerns. Under the plain language of the regulation, a licensee would be required to go through a costly and time-consuming amendment process any time it adds lighting, changes flooring or surfaces, reconfigures a back office or break room, or makes any number of possible physical modifications that have no effect on security or other regulatory concerns. These regulations should be re-written to require amendment only for physical modifications that add or removes space to areas where cannabis is dispensed, stored, or produced; or that change the location of external doors; or which materially changes the security system.

The proposed regulations at 7.34.4.8(R)(2) and .17(J) also require amendment upon the change in ownership of facilities. Transfers in building ownership by the third-party, arms-length landlord of a cannabis business has no regulatory import and should not require a filing by the business. This requirement appears to come from the Department's concerns about disclosure of the identity of related parties to cannabis businesses. The Department should make a related party rule to focus on the circumstances with which it actually interested, and eliminate rules like these that burden licensees engaged in standard business practices with arms-length third parties. Similarly, licensees should not be required to disclose all persons with indirect interest in facility ownership, whose identities may not be known to them in the context of an arms-length lease.

The proposed regulations at 7.34.4.8(R)(2) requiring amendment for changes in LNPP directors is also excessive and burdensome to the ordinary course of business for LNPPs, in which directors resign without notice or must be replaced immediately for other reasons. Moreover, other rules already require background checks and issuance of an employee card for new directors. The Department's additional needs to know about director changes could be satisfied by a notice requirement.

5. Issues with Laboratory Testing Requirements

a. <u>Rules specifying when testing is required are ambiguous, and unworkable.</u>
Proposed rule 7.34.4.10 appears to require testing before any transfers of cannabis can occur. It expressly requires testing of dried cannabis before it is manufactured into a CDP. It is wasteful and to no benefit to require testing of dried cannabis (either flowers or trim) which is destined for extraction. The regulatory needs are met by testing the extract or other resulting CDPs prior to their being released for distribution to patients. This rule should be rewritten to require testing before any distribution of cannabis of CDPs to patients, and otherwise permit licensees to transfer untested cannabis on a wholesale basis between themselves, if they so desire, and to not test dried cannabis that will be used to make an extract.

b. <u>Microbiological Testing Requirements/Action Levels are Excessive</u>
The Department has specified action levels for microbiologicals that exceed what some other states require. Over-regulation in microbiological testing adds unnecessary costs for production activities and remediation. Unnecessary remediation can also adversely impact cannabis medicine.

The recommendations from the Cannabis Safety Institute white paper should be adopted, which also comport with the extensive experience of Scepter with respect to samples which have failed microbiological screening, for which the lab often engages in follow-up investigations:

1. Cannabis should be tested for four species of Aspergillus: A. flavus, A. fumigatus, A. niger and A. terreus. Together these species are responsible

for the vast majority of cases of invasive pulmonary aspergllosis and they are the only pathogens that represent a clear and certain danger on cannabis.

2. Cannabis should be tested for total generic E. coli. Samples with levels above 100 cfu/gram should be rejected. This is the one indicator test that we recommend. Detection of significant levels of E. coli are strong evidence of problems during growing or processing. E. coli is now accepted to be the optimal indicator organism for the identification of possible fecal contamination. Were pathogenic bacteria to be present, they would likely have arrived through this type of pathway, therefore samples positive for E. coli are indicative of general production problems that need to be addressed.

3. Cannabis should be tested for Salmonella. The odds of salmonella infection from cannabis are very low. Nonetheless, it is the one bacterial pathogen that poses a potential threat to cannabis smokers. There is precedent for salmonella association with cannabis. It is highly infectious and can cause disease with as low a dose as one single cell. It is hardy and resistant to dessication.

4. Testing cannabis for total yeast and mold is unnecessary and unjustified. Total yeast and mold tests detect only a small fraction of the fungal species in the environment, and do not correlate with the presence of pathogenic species. The only pathogenic mold species on Cannabis are types of Aspergillus that should be tested for separately. Molds can potentially be a cause of allergic hypersensitivity reactions, but there is no evidence that these are mediated by smoking. In the alternative, the combined total yeast and mold count action level should be relaxed, as it is not indicative of health risks, and is often triggered by the presence of benign yeasts.

c. Routine Mycotoxin Testing Should be Eliminated

As of this fall, Scepter Lab had conducted 15,649 mycotoxin tests on medical cannabis samples since the requirement was implemented in NM, at a cost to producers of $704,205,00, without registering a single positive result. To our knowledge, there has not been a single positive mycotoxin test result by any NM cannabis laboratory. Confident Cannabis, a company providing a popular cannabis laboratory software platform, says its records only show about 100 positive results for mycotoxins across all of its client laboratories, and none arising from activities in dry climates like ours. Confident Cannabis states that it has a 40% market share of labs across the U.S. and Canada.

Kathleen O'Dea, who has advanced credentials in microbiology and has worked in microbiology outside the cannabis industry as well as operating Scepter, has reviewed the scientific literature and concluded that mycotoxins are rarely found in cannabis because

the material does not support the growth of the organisms that produce mycotoxins or the production of mycotoxins. The Cannabis Safety Institute states that "seedless cannabis plants are not capable of supporting aflatoxin production, because they lack the high oil content necessary for replication."

Moreover, The Cannabis Safety Institute also finds that "Aflatoxins will degrade by the heat of smoking or decarboxylation, if any were present."

Thus, a requirement for routine mycotoxin testing, at very material expense, is arbitrary and capricious and not supported by any reasonable assessment of risks.

d. Routine Heavy Metal Testing is Unjustified

The Cannabis Safety Institute only recommends heavy metal testing where cannabis is grown outdoors on land where there has been historical use of arsenic based pesticides that has accumulated in the soil. (Arsenic-based pesticides are today banned in the U.S.)

To my knowledge, all medical cannabis cultivated indoors in our state is grown in media obtained or produced from commercial products marketed for this purpose. All of the medical cannabis I have seen being grown outdoors in New Mexico has also been grown in such media, in containers, and not in the native soil. The MCP, which has visited all outdoor production sites, can verify that cannabis is rarely, if ever, grown in native soil better than I.

It is not possible for cannabis grown in commercial growing media to become contaminated with heavy metals. It is arbitrary and unjustified for the Department to require routine heavy metal testing , which will impose very significant expenses on the testing laboratories and on the producers, in the absence of any plausible risk. Scepter estimates the cost of the equipment necessary to implement heavy metal testing will be well in excess of $100,000 to purchase or at least $30,000/mo to lease.

A reasonable rule that protects patients from heavy metal-contaminated medicine would target soil, not the cannabis. The Department could (and should) require any producer proposing to grow in native soil to have that soil tested for heavy metals before the production area is licensed. Such testing, since it would not involve any cannabis, could be provided by any nationally accredited laboratory.

e. Pesticide Testing Should be Refined

The Departments regulations permit the use of any licensed pesticide, but require testing for only 13 substances. This is both too many and too few. Too many, when it is wasteful to require testing for substances that have not been used in the cultivation of a particular batch of cannabis, and too few, when the rules allow the use of substances that will not be tested for. The Department is justified in seeking to prevent patients from being exposed to pesticide residues, but the proposed rules are not well-tailored to this end.

In addition, the equipment and supplies to implement pesticide testing are expensive to obtain. The list price for the equipment is $450,000. It is not possible to economically amortize an upfront cost like that over the volume of testing samples in New Mexico. Scepter estimates it will need to charge $250 per sample for pesticide testing.

The Department should withdraw the pesticide testing rule and convene a work group of patients, producers, and testing laboratories to arrive at a workable rule.

f. Requiring Specific Testing Technologies and Samples is Unjustified

The proposed rules mandate that laboratories use certain technologies for required tests (Table 7). This is arbitrary and unjustified. The Department has a legitimate regulatory interest in assuring that testing is performed accurately. But laboratories should be permitted to utilize any technology that can demonstrate sufficient testing accuracy. By mandating specific technologies, the Department may require a laboratory to incur unnecessary costs to replace equipment that is functional, and will certainly discourage innovation that can lead to greater testing efficiency.

In a specific example of how this mandate is unjustified, Scepter currently uses the ELISA method for detecting mycotoxins. This method is fully validated for use in cannabis and generates numerical data that "matches" with HPLC. Scepter has been validated by NMDOH and its Scientific Laboratories Division as being capable of producing accurate results in mycotoxin testing using its current method. Other states allow the ELISA method.

The first steps in the ELISA method are procedurally identical to the HPLC method. The only difference is how the active material is “read" - HPLC or spectrophotometer. From interaction with DOH’s Scientific Laboratories Division, Scepter knows that it prefers the HPLC, but there is nothing "wrong" or "invalid" with the ELISA method. It would be a significant hardship and expense for Scepter replace its spectrophotometers with a new detector for its HPLC machine, and it would take months of validation studies to bring this on-line. Mandating certain methods and rejecting others which are completely functionally equivalent is the textbook definition of “arbitrary” government conduct.

Next, the Department should also not mandate specific sample quantities in rule. There is no plausible reason for doing so. Sample sizes should be what is determined by the testing laboratory to be necessary for it to provide complete and reliable results. Any amount in excess of this is effectively an unnecessary expense to producers, and serves to increase the cost of medicine to patients. Mandating excess sample sizes, like all regulations that increase testing costs, incentivizes producers to find ways to test less, which is ultimately contrary to the objectives for the testing regulations.

g. “Quality Assurance Testing” is of Limited Value

The Department proposes to test, or obtain tests of, cannabis and CDPs it obtains from producers and manufacturers in 7.34.4.12. The results of such testing are not indicative of the testing accuracy of laboratories which may have tested a sample from the batch

which is now being examined by the Department, nor are such results indicative of anything other than how that singular, individual product tests. Cannabis is biological material and will differ by as much as 30% from the top of the plant to the bottom or from plant to plant. That portions of a harvest may be exposed to different conditions during drying, curing, and other processing also introduces non-uniformity.

h. End Product Testing is Unjustified

The Cannabis Safety Institute recommends against end-product testing of cannabis edibles (food products), and recommends instead requiring production under sanitary conditions, which the Department elsewhere does in its rules. *Microbiological Safety Testing of Cannabis*, Cannabis Safety Institute, May 2015. This approach follows the best practices in the production of commercial foodstuffs. Cannabis Safety Institute states:

> Cannabis food products are as likely to become contaminated as any other processed or prepared commercial food product. But because of its unique attributes, Cannabis is the least likely component to be the source of contamination in any food product. [emphasis in the original.] Cannabis is present in foods as an extract of the plant material. This plant material is dried to a safe level before extraction. And then either during or after extraction it is usually subject to a decarboxylation process that serves as a heat-kill step. The vast majority of the extraction processes are themselves sterilizing. Once these extracts are added to food, the food can always be mishandled or subject to "temperature abuse", which raises the chances of contamination. But these are factors facing all foods, and the only pathogen of real concern on Cannabis (Aspergillus) is not infectious by the oral route. Cannabis food products should be regulated as all food products are . . .

i. Repeat "Initial Demonstrations of Capability" are Unjustified

The proposed rules at 7.34.4.19(F) require an Initial Demonstration of Capability (IDC) whenever a laboratory is initially approved for a platform, or when equipment is moved, or a new instrument installed. The rules at 7.34.4.17(C)(17) require documentation of IDCs to be provided with renewal examinations. This specific rule should be eliminated, as there is no benefit to requiring the resubmission of documentation for a previous IDC with renewal, assuming that this rule is requesting resubmittal. If it is requesting a new IDC, that is not only inconsistent with the IDC rules at 7.34.4.19(F), it is arbitrary and unjustified.

"Initial Demonstration of Capability" means just that – an initial demonstration. It is reasonable for NMDOH to require a laboratory to prove that it can perform testing using a particular platform with accuracy, and under a range of concentrations, prior to approving the lab for that platform. An IDC is a demonstration that a laboratory has the basic capabilities, which are testing machines and other equipment, consumables, and standard operating procedures, to test with accuracy using a platform. If the laboratory is not changing any of these parameters, then there is no reason to require another initial demonstration. In satisfying an IDC, a laboratory makes a focused effort to produce

specific demonstrations outside of its normal commercial operations. Thus, a redundant IDC has no real value in demonstrating the accuracy of a laboratory's routine operations. Scepter's experience, which comports with common sense, is that once a laboratory has developed the ability to satisfy an IDC requirement for a platform, it can always replicate that showing, given sufficient expenditure of time and money. Redundant IDC requirements are effectively a bunch of "busy work" providing a purely superficial appearance that the Department is assuring that a laboratory is maintaining operational accuracy.

For these reasons, it is also unjustified for the Department to require a new IDC whenever equipment is relocated. IDCs are expensive in time and materials. They primarily test procedures, which will not have changed with the movement of equipment. Concerns that testing machines may have been affected by the jostling of being moved between locations or by their position in the laboratory relative to other machines and HVAC can be addressed with much simpler and less costly confirmatory analyses.

6. Other Comments

7.34.4.7(F), definition of Applicant. This definition is only needed and used with respect to patients and caregivers. There is no need to include producer applicants in the definition, and it creates ambiguity.

7.34.4.7(R) and (T), definitions of diversion and inversion are over-broad, and make the definitions less useful, and potentially subject to void for vagueness challenges if any transfer of cannabis that is unlawful; i.e., in violation of any rules, is a diversion/inversion. The Department should narrow these definitions to pertain to transfers from or to persons who are not licensed entities.

7.34.4.7(EE). For some time, the Department has used "Director" as the title of the person who administers the program, the rules should be consistent.

7.34.4.7(FF). The LECUA requires that the Department issue patient registrations upon a practitioner's certification; it would be unlawful for the medical director to exercise the power provided in this definition.

7.34.4.7(NN). It exceeds statutory authority for the Department to exclude petitions for covered conditions from persons who are not residents.

7.34.4.8(A)(2) and (K). The Department reasonably licenses multiple production facilities under a single license. Concurrent operation of an indoor and an outdoor grow is common in the program, and is desirable for allowing producers to produce medicine to meet patient needs year-round, at the lowest cost. The rules at .8(A)(2) should state "one or more facilities" and not imply a restriction to "a facility" for clearness. In addition, at subpart K, the rules should not restrict production to one facility, nor allow facilities at the Departments arbitrary "discretion." .8(A)(2) should be rewritten to state "A producer shall conduct its operations only at the physical locations approved by the

department, which facilities shall be reasonably necessary to supply the cannabis needs of the patients served by the producers, and whose numbers and locations shall not unreasonably burden the department's ability to monitor production activities."

Thank you for your attention to these comments.

Sincerely,

Jason Marks

[EXT] NMCCC Response to DOH Proposed Rule Changes to MCP

Ben Lewinger <ben@nmcannabischamber.org>

Thu 11/21/2019 10:05 PM

To:comment, MCP, DOH <MCP.Comment@state.nm.us>;

Cc:Zurlo, Dominick, DOH <Dominick.Zurlo@state.nm.us>; Kunkel, Kathy, DOH <Kathy.Kunkel@state.nm.us>;

1 attachment

NMCCC Response to DOH Proposed Rule Changes_11.22.2019.pdf;

Secretary Kunkel, Director Zurlo –

Attached is the NM Cannabis Chamber of Commerce's response to the proposed rule changes to the MCP. These comments were voted upon by NMCCC members at our quarterly membership meeting this week.

I want to echo the sentiment at the beginning of this letter – our members value and appreciate the hard work by DOH staff in creating these proposed changes, and the transparency and professionalism throughout this process.

We look forward to the opportunity to further discuss comments herein, if there is opportunity, and look forward to a continuing positive working relationship with DOH.

Best,

NEW MEXICO
CANNABIS CHAMBER OF COMMERCE

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New Mexico Department of Health
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Submitted via email to MCP.comment@state.nm.us
CC: MCP Director Dominick Zurlo, DOH Secretary Kathyleen Kunkel

NEW MEXICO
CANNABIS CHAMBER OF COMMERCE

November 21, 2019

RE: Proposed repeal and replacement of various rule sections of Department rules 7.34.2, 7.34.3, and 7.34.4 NMAC.

Ms. Sundberg,

On behalf of the membership of the New Mexico Cannabis Chamber of Commerce (NMCCC), this letter is our organization's submission of comments to the proposed rule changes to the Medical Cannabis Program. These comments were voted upon by NMCCC membership.

NMCCC recognizes and appreciates the continuing efforts of the Department of Health to improve the state's Medical Cannabis Program.

In general, NMCCC is concerned that new labeling requirements are unrealistic, and that new testing requirements are unnecessary, excessive, and will result in more expensive medicine, driving patients to the illicit market. Below are specific points of concern.

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Producer Licensing; General Provisions – 7.34.4.8
Regarding the destruction of usable cannabis and cannabis plants (M.), the requirement to retain a video record for 120 days would require significant digital storage. NMCCC recommends DOH manage storage of video data, or that digital photographs recording destruction of wastage be used instead. Furthermore, if plants are destroyed to eliminate contamination, the holding period could potentially put other plants at risk.

Regarding attestation that producers and manufactures prohibit employees and contractors from being under the influence of drugs or alcohol in the workplace (O.13., 7.34.4.9.32), as do many industries in New Mexico, cannabis producers employ individuals enrolled in the Medical Cannabis Program. As such, "under the influence of drugs" could be taken to mean individuals that have legally consumed medical cannabis for a qualifying condition, regardless if the individual is impaired or not. NMCCC views this as an opportunity to make an important distinction between "drugs" and "medical cannabis" and would like to see language that is more inclusive of patient-employees enrolled in the MCP.

Non-Profit Producers; Minimum Standards for Production of Cannabis – 7.34.4.9
This section contains requirements that are unclear as to how to interpret and unclear as to how DOH plans on enforcing, such as plumbing and handwashing, the latter that should pertain to product handling and packaging, but not farming activities (repeated in 7.3.4.4.15).

Testing of Usable Cannabis – 7.34.4.10
NMCCC shares the goal of cultivating, manufacturing, and selling medicine that is safe for the end user. Overall, the proposed changes to testing regiments are largely unnecessary, excessive, and would be

cost prohibitive to patients, forcing more individuals to turn to the illicit market. In New Mexico, plant count limits and comparatively few cultivators and manufacturers make for small batches, which disproportionally affects the cost per gram to enrolled patients.

One of the labs is conservatively estimating an additional per batch price increase of over $700 for a full panel of testing. Based on data and analysis provided by NMCCC members, for the average manufacturing license holder, increased testing costs, combined with the new mandatory minimum product to be supplied for testing, will result in an increased testing cost of nearly $4 million per year for independent manufacturers. In addition to lost revenue to the state from unnecessary wastage, patients would pay an additional $5-$8 per gram of manufactured product, which is unacceptable.

Since neither of the approved laboratories in New Mexico are currently capable of testing for pesticides or heavy metals, the section on staggered implementation is important, but it is concerning that rules could potentially go into effect with possibility of compliance.

Requirements for the same testing on manufactured products wherein there is no possibility of a different result from testing on dried usable cannabis should be removed, as this redundancy would do nothing but increase cost to patients. NMCCC recommends that flower and trim be delivered to manufacture license holders with disclosures for all testing performed and a statement regarding pesticide use.

In terms of microbiological testing requirements, NMCCC supports testing recommendations from the Cannabis Safety Institute, which spells out testing for four types of Aspergillus, total generic E. coli, and Salmonella. The only pathogenic mold that could appear on cannabis is Aspergillus, so total yeast and mold test are unnecessary. Furthermore, the current state-approved laboratories agree that the current 1g sample is sufficient to perform all necessary microbial panels.

Regarding testing for mycotoxins, it's been reported that despite tens of thousands of tests by both the state-approved laboratories, there has never been a positive hit for the presence of mycotoxins. Furthermore, if mycotoxins weren't present in the dried usable cannabis batch, they would not be present in the manufactured product that came from the same batch, so the second series of post-manufacture testing is unwarranted.

The provision for random testing of finished cannabis derived products (C.8.) puts an unfair onus on producers and manufactures that is unseen in any other industry. Food safety inspectors inspect food, and DOH should follow a similar protocol, not put the entire responsibility for random testing on producers and manufacturers.

Regarding the increase of quantities of cannabis for sampling (Table 7. Minimum Test Sample Size), this is perhaps the most concerning set of proposed changes. Both state-approved testing facilities attest that the proposed sample sizes are far too large, creating a logistical challenge for testing facilities to handle significantly more waste. Also, the increase in sample size would potentially hurt the supply of medicine for patients, particularly for manufactured products (could be interpreted as 1% of dried cannabis, but up to 20% of concentrate per batch).

Regarding heavy metal testing, the NMCCC doesn't believe this is a necessary batch test. Heavy metals in dried usable cannabis would either come from soil or the material that cannabis is grown in, or water used in the production of cannabis. We recommend testing those two inputs for producers on a regular

basis instead of testing all batches. Again, this is an unnecessary test that will only increase the price of medicine for consumers without increasing patient safety.

The section on Remediation; subsequent testing (F) does not include other commonly accepted processes for remediation, such as UV. Also, the language is confusing and awkwardly worded.

Labeling – 7.34.4.16

While the NMCCC supports empowering patients with pertinent product information and keeping the general public safe with clear labels indicating THC content, new labeling requirements set forth in the proposed changes are not realistic in terms of available space on many products. For example, the amount of information specified in Table 8 is not possible to include on smaller containers at 8-point type or larger. Furthermore, the information on the proposed label and Drug Information Sheet is largely duplicative and wasteful.

NMCCC recommends permitting a 6-point type font size on labels, including "Cannabis Facts", laboratory testing data for THC and CBD only, warnings and the barcode on labels directly affixed to products. The Drug Information Sheets could be provided for each product as proposed in Table 9, including laboratory testing on other cannabinoids, stapled to the bag. This process is consistent with labeling and information included in doctor-prescribed pharmaceuticals that individuals purchase at pharmacies.

Department-Approved Testing Laboratories; Instrumentation; Initial Demonstrations of Capability – 7.34.4.17

NMCCC believes that the state should not be specifying exactly what test instrumentation be used when there are other scientifically-validated methods that produce the same or similar data. The cost of purchasing, validating, and training with new equipment, when existing equipment and processes produce equally valid data, is a sunk cost that will accomplish nothing but increase the price of medicine for consumers.

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These concerns represent a comparatively small number of the total proposed changes. NMCCC members remain grateful to the DOH for working diligently to improve the MCP and appreciate the Department's efforts in this regard. In particular, membership is pleased with the thoughtful inclusion of reciprocity with other states' medical programs. We look forward to a continued positive working relationship with the New Mexico Department of Health.

Respectfully,

Ben J. Lewinger
Executive Director
New Mexico Cannabis Chamber of Commerce

November 22, 2019

Dear Hearing Officer,

Please receive the following for public comment for the proposed repeal and replacement of MCP rules at 7.34.2, 7.43.3 and 7.34.4 NMAC.

These comments are being submitted with regard to proposed cannabis testing requirements. Although the laboratories were called to a meeting in September to preview the proposed testing requirements and made verbal comments, the laboratories were only provided with one hour for commentary and that included having to read the proposed rules in the meeting in order to comment.

The laboratories were also told that comments needed to be submitted by October 4, 2019, which I believe would mean that they would not be included in the public record since the rules had not been filed yet.

Even after making verbal and written comments to the NMDOH regarding the problematic proposals, the NMDOH did not "hear" the objections or incorporate any changes in the proposed rules that were subsequently published.

Accordingly, I am providing you the full text of our comments along with the comments made by Scepter's attorney, Jason Marks.

The overarching concern expressed by the laboratories is that much of the testing is unnecessary, expensive, not supported by empirical data and will not enhance or ensure patient safety. Even though other states may have imposed similar or identical regulations, they have done so without regard to any data supporting the necessity of such testing. Merely copying another state is not adequate justification for making new rules here. Furthermore, New Mexico produces a limited amount of cannabis due to the limited number of growers and plant limits. This makes the cost of testing significantly higher than in other states. There is no rational, nor scientific, basis for imposing heavy metal testing, mycotoxin testing or total yeast and mold testing. Heavy metals are seen in 0.11% and mycotoxins at 0.4% of the samples nationally and are likely false positives. New Mexico producers have paid Scepter over $704,205.00 to test 15,649 samples for mycotoxins without finding a single positive result. Cannabis plant material will not support the formation of mycotoxins. Period. There is no rationale basis for requiring this test. Likewise, heavy metals, except the price tag will be much, much higher. Cannabis grown indoors in artificial media will not produce heavy metals. Whether other states impose such requirements should not be the benchmark. Good science and empirical data should.

The following are attached to this letter:

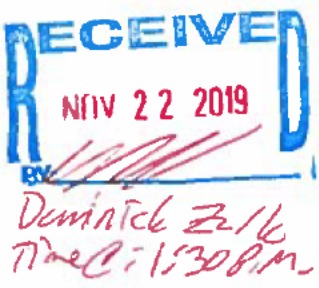
Letter to Secretary Kunkel dated October 4, 2019.

Letter to Andrea Sundberg dated November 22, 2019

Letter from Barry Dungan dated October 4, 2019.

Respectfully submitted,

Kathleen O'Dea



October 4, 2019

Dear Secretary Kunkel,

I am the Director and owner of Scepter Lab. We have conducted testing on over 50,000 medical cannabis samples since November 2014, and began testing when there were only 7 other laboratories in the country. We have watched state after state adopt and implement rules without any input from scientists or any empirical data showing that such testing standards are necessary. Although some of your proposed testing requirements will provide an added measure of protection to the public health, some current and proposed testing requirements do nothing to advance public health, will increase the cost of patient medicine and could encourage manipulation of samples by the growers. More rules or more stringent rules will not insure a safe product. **Without control over who takes the sample and who submits it to the laboratories, the growers can simply continue to "doctor" samples, substitute samples or find other ways to circumvent the passing requirements.**

For example, imposing new testing requirements cannot stop a production facility from using a pesticide that is not on the list in order to pass a pesticide test and circumvent the list. That said I believe that a reasonable number of pesticides should be tested for, if for nothing else, but to placate the patients and regulators, but I do not believe that testing will tell anything at all about the purity of the batch. Accordingly, I think the most important change you could make to the regulations is to clamp down and control what is submitted for testing as is required by almost every state. Adding tests without controlling samples will achieve nothing and is just folly and may only make for some good temporary "pr" for the Department.

The following are my comments and recommendations:

- **Quality Assurance testing**- Random testing of products at Departments discretion – do not adopt
    - We do not support "secret shopping" or believe that it provides any useful information except for how that singular, individual product tests. Cannabis is biological material and will differ by as much as 30% from the top of the plant to the bottom or from plant to plant. A better approach is to regulate and control how the samples are taken and submitted to the laboratory together with sampling criteria. All rec states and most medical states require that samples be taken by laboratory personnel in a prescribed manner. It is almost impossible for a producer to "doctor" or cherry pick a sample for submission under this system. Until control is exercised over sample submission, cheating will be the order of the day.
- **Mycotoxin testing**
    - Testing laboratories will utilize HPLC, LCMS, or LCMSMS instrumentation for the testing of mycotoxins
    - A laboratory will use no more than two significant figures to report a positive mycotoxin result
    - A laboratory will report a non-detect of a mycotoxin as less than the laboratory minimum reporting level

- The laboratory's minimum reporting level must be equal to or less than 1 µg/kg
- A laboratory will also report a PASS or FAIL evaluation with the reported result

Mycotoxin testing should be eliminated entirely. The Cannabis Safety Institute whitepaper recommends testing only for the organism that produces the toxin. "Aflatoxins will degrade by the heat of smoking or decarboxylation if any were present. But seedless cannabis plants are not capable of supporting aflatoxin production, because they lack the high oil content necessary for replication."

Our laboratory has conducted 15,649 mycotoxin tests at a cost of **$704,205.00** to the producers since requirements were implemented. To date we have not found a single positive result. Again, not one failure. Rio Grande Analytics has not found a single positive result. This is an ample scientific database to conclude that the material does not support the growth of the organism or the production of mycotoxins. Continued testing does not improve the quality of the material or the public health. There is no rational basis to support this requirement, much less, to require a more expensive method and instrument than is currently approved.

We currently use the ELISA method for detecting mycotoxins. This method is fully validated for use in cannabis and generates numerical data that "matches" with the HPLC. The first steps in the ELISA method is procedurally identical to the HPLC method. The only difference is how the active material is "read" – HPLC or spectrophotometer. We know the state scientific laboratory prefers the HPLC but there is nothing "wrong" or "invalid" with the ELISA method. It would be a significant hardship for us to have to replace our spectrophotometers with a new detector for our HPLC and it would take months of validation studies to bring this on-line. ANY SCIENTIFICALLY VALIDATED METHOD SHOULD BE ACCEPTABLE AND THE STATE SHOULD NOT REQUIRE A PARTICULAR TYPE OF INSTRUMENT IF ANOTHER METHOD ACHIEVES THE SAME VALID RESULT.

BECAUSE THERE DOES NOT APPEAR TO BE A SCIENTIFIC BASIS OR HEALTH REASON FOR THIS RECOMMENDATION, AND BECAUSE OTHER STATES ACCEPT THE ELISA METHOD, I BELIEVE THE SCIENTIST FROM THE STATE SCIENTIFIC LABORATORY IS CONTINUING TO TARGET OUR TESTING CHOICES AND SHOW BIAS AGAINST US. Accordingly, if this is implemented we will have no choice but to take some form of legal challenge.

- **Heavy Metal testing will be required on all usable cannabis:**

Table 5. New Mexico Department of Health Medical Cannabis Program Heavy Metal Testing Requirements					
Heavy Metals	Elemental Symbol	IUPAC Name	CAS Number	Action Level (µg/g) or (ppm)*	Method Reporting Level (µg/g) or (ppm)*
Arsenic	As	arsenic	7440-38-2	2.0	1.0
Cadmium	Cd	cadmium	7440-43-9	0.8	0.2
Lead	Pb	lead	7439-92-1	1.2	0.2
Mercury	Hg	mercury	7439-97-6	0.4	0.1
*Micrograms per gram (µg/g) of sample is equivalent to parts per million (ppm).					

Heavy metal testing should not be required or should be phased in. The Scientific Laboratory Division should be required to provide empirical data from indoor grown cannabis that establishes that any heavy metals above the threshold actually exist. Only then should the Department adopt and implement such a rule.

The Cannabis Safety Institute only recommends heavy metal testing where cannabis is grown outdoors in the ground where there has been historical use of arsenic based pesticides that has accumulated in the soil. Almost all cannabis grown in this state is grown in artificial soil indoors. This will again be another test imposed by regulators that will generate tens of thousands of "zeros", will cost the patients and will not improve the purity of the product. Even the cost to lease an ICP-MS will be in the range of $30,000-$40,000 per month, but please understand that no financial institution will lend money or bank with cannabis businesses, so it is unclear whether we would be in a position to acquire such equipment at all.

It will take at least three months to bring this on-line and will require an outlay of a minimum of $90,000 before a single sample can be processed. Our laboratory only processes approximately 500 samples per month. The lease expense alone will add $60 to the cost of the panel. Add to that labor, supplies, and overhead will require a charge of at least $150.00 per sample for this one test. The annual cost to producers will be $1,800,000.00. The fact that there is no showing anywhere that indoor grown cannabis is contaminated with heavy metals is an unreasonable requirement imposed by the state with no demonstrable public health benefit.

- **Pesticide testing on dried usable cannabis (i.e. flower, shake trim etc.)**
  - Testing laboratories will utilize HPLC, LCMS, or LCMSMS instrumentation for the testing of pesticides.
  - A laboratory will use no more than two significant figures to report a positive pesticide result.
  - A laboratory will report a non-detect of a pesticide as less than the laboratory's minimum reporting level.
  - The laboratory's minimum reporting level must be equal to or less than 100 µg/kg.
  - A laboratory will also report a PASS or FAIL evaluation with the reported result.

- Pesticides pose a health hazard to the consumer and are being used on cannabis. The problem with this testing is two-fold: there are 3,126 pesticides so which ones are most appropriate to test for? And how do you stop the growers from using a pesticide that is not on the list once you publish a list?

- Your proposed list seems reasonable but your implementation date is unreasonable. The lead time for ordering an appropriate instrument is at least three months, the time for set up is a minimum of three months and the price tag is $450,000. We do not have an available lender or investor. Even if the manufacturer would extend credit the monthly fee would be $50,000. We currently process 500 samples a month which would not come close to covering this expense even if we added $100 to each sample plus the cost to actually do the test. Our lab would need to charge $250 for each sample. We are a small state with plant limits. Not all producers are in compliance with 5 pound per batch testing requirement. Unless the sample volume increases there would be no way to cover the lease cost.

Table 6. New Mexico Department of Health Medical Cannabis Program Pesticides Testing Requirements

Targeted Pesticide	Common Chemical Name	CAS Number	Action Level (µg/kg)	Method Reporting Level (µg/kg)
Abamectin	avermectin B_{1a} & avermectin B_{1b}	71751-41-2	500	100
Azoxystrobin	azoxystrobin	131860-33-8	200	100
Bifenazate	bifenazate	149877-41-8	200	100
Etoxazole	etoxazole	153233-91-1	200	100
Imazalil	chloramizole	35554-44-0	200	100
Imidacloprid	imidacloprid	138261-41-3	400	100
Malathion	malathion	121-75-5	200	100
Myclobutanil	myclobutanil	88671-89-0	200	100
Permethrins	*cis*-permethrin & *trans*-permethrin	52645-53-1	200	100
Spinosad	spinosyn A & spinosyn D	168316-95-8	200	100
Spiromesifen	spiromesifen	283594-90-1	200	100
Spirotetramat	spirotetramat	203313-25-1	200	100
Tebuconazole	tebuconazole	80443-41-0	400	100

*Micrograms of pesticide per kilogram (µg/kg) of sample is equivalent to parts per billion (ppb).

- **End product testing-** required on all usable cannabis products:
  - Dried usable cannabis: Microbiological test, Potency test, Mycotoxin test, Pesticide test, Heavy metals test, and moisture content analysis.
  - Concentrated cannabis derived products: Microbiological test, Potency test, Mycotoxin test, Heavy metals test, and residual solvents test.
  - Cannabis derived products: Microbiological test, Potency test, Heavy metals test, and Mycotoxin test.
  - Homogeneity of potency for cannabis derived products

Metal and mycotoxin testing should not be required.

End-product testing of cannabis edibles should not be done.

The Cannabis Safety Institute does not recommend end-product testing of cannabis edibles (food products). They state: "Cannabis food products are as likely to become contaminated as any other processed or prepared commercial food product. But because of its unique attributes, Cannabis is the least likely component to be the source of contamination in any food product. This plant material is dried to a safe level before extraction. And then either during or after extraction it is usually submect to a decarboxylation process that serves as a heat-kill step. The vast majority of the extraction processes are themselves sterilizing. Once these extracts are added to food, the food can always be mishandled or subject to "temperature abuse", which raises the chances of contamination. But these are factors facing all foods, and the only pathogen of real concern on Cannabis (Aspergillus) is not infectious by oral route. Cannabis food products should be regulated as all food products are."

- **Sample Size increase-** Based on recommendations from United States Pharmacopeia expert panel.
    - Dried usable cannabis: 25.5 grams / 5 lb batch = 1.0% of harvest.
    - Concentrated cannabis derived products: 23.0 grams or 23.5 grams / batch.
    - Cannabis derived products: 23.5 grams per batch

Table 7. New Mexico Department of Health Medical Cannabis Program Minimum Test Sample Size			
Targeted Parameter	**Sample Matrix**	**Analysis Platforms (Instrumentation Used by Lab)**	**Minimum Amount Required for Testing (grams)**
Cannabis Potency	dried usable cannabis	HPLC, LCMS	1.0
	concentrate	HPLC, LCMS	1.0
	cannabis-derived products	HPLC, LCMS	1.0
Cannabis Moisture Content	dried usable cannabis	n/a	1.0
Mycotoxins	dried usable cannabis, concentrate, or cannabis derived products	HPLC, LCMS, LCMSMS	1.0
Residual Solvents	concentrate	GC-FID, GC-PID/FID	1.0
	concentrate	GCMS	0.5
	cannabis-derived products	GC-FID, GC-PID/FID	5.0
	cannabis-derived products	GCMS	1.0
Absence of Salmonella spp. & E. coli	dried usable cannabis, cannabis derived product	Culture, Biochemical, Antibody, or Nucleic Acid- based assays Must be Validated Microbiological Methodology such as FDA, USP, AOAC, or equilivant.	10.0
Total Aerobic Microbial Count **Total Combined Yeast & Mold Count** **Bile-tolerant Gram-negative Bacteria** **Total Coliforms Count**	dried usable cannabis, concentrate, or cannabis - derived products	Direct Culture, Indirect Culture, or non-Culture based. Must be Validated Microbiological Methodology such as FDA, USP, AOAC, or equilivant.	10.0
Pesticides	Dried usable cannabis	HPLC, LCMS, LCMSMS	2.0
Heavy Metals	dried usable cannabis, concentrate, cannabis derived product	ICP-MS, FIMS	0.5
Mnimum Test Sample Size May Change if A Validated Method is Approved by NMDOH MCP			

Moisture content is not the current acceptable methodology for determining quality or shelf life. Water activity is a method required by most states, and should be adopted. According to the Cannabis Safety Institute: "Water activity can be used as a marker for overall microbial levels. Plant material with high water activity will support microbial growth. Because the drying step is one piece of insurance against microbial dangers associated with Cannabis, it makes sense to require that this step be complete. The majority of commercially sold Cannabis is dried to water activity levels that are below the minimum threshold for any type of microbial replication. Very few bacterial or fungal species can replicate between Aw 06 and AW0.7. We recommend that all curing processes aim to produce flower material under Aw 0.6."

We agree with Barry Dungan from RGA: " For the microbial panels (Salmonella, E. coli, RAC, RYM, EB, EC) I feel the current amount of 1g is sufficient to do the test. We currently have to do very large dilutions to accurately count colonies on petrifilm."

With regard to microbial panels we believe the recommendations from the Cannabis Safety Institute white paper should be adopted:

1. **Cannabis should be tested for four species of Aspergillus**: A. flavus, A. fumigatus, A. niger and A. terreus. Together these species are responsible for the vast majority of cases of invasive pulmonary aspergillosis and they are the only pathogens that represent a clear and certain danger on cannabis.

2. **Cannabis should be tested for total generic E. coli.** Samples with levels above 100 cfu/gram should be rejected. This is the one indicator test that we recommend. Detection of significant levels of E. coli are strong evidence of problems during growing or processing. E. coli is now accepted to be the optimal indicator organism for the identification of possible fecal contamination. Were pathogenic bacteria to be present, they would likely have arrived through this type of pathway, therefore samples positive for E. coli are indicative of general production problems that need to be addressed.

3. **Cannabis should be tested for Salmonella**. The odds of salmonella infection from Cannabis are very low. Nonetheless, it is the one bacterial pathogen that poses a potential threat to cannabis smokers. There is precedent for salmonella association with cannabis in both this early epdemic and in very recent microbial sequencing data.. It is highly infectious and can cause disease with as low a dose as one single cell. It is hardy and resistant to dessication.

4. **There is no need to test Cannabis for total yeast and mold**. Total yeast and mold tests detect only a small fraction of the fungal species in the environment, and do not correlate with the presence of pathogenic species. The only pathogenic mold species on Cannabis are types of Aspergillus that should be tested for separately. Molds can potentially be a cause of allergic hypersensitivity reactions, but there is no evidence that these are mediated by smoking.

7.34.4.15 DEPARTMENT-APPROVED TESTING LABORATORIES; GENERAL PROVISIONS:

- **An Initial Demonstration of Capability (IDC) includes the following elements for all required tests:**
  - **Demonstration of Method Calibration:**
    - Minimum of five calibration points consisting of five different concentration levels of target compounds
    - The calibration range must include a low calibration point equal to, or less, than the required Minimum Reporting Level for each targeted compound
    - The calibration range must include a calibration point equal to the Action Level for each targeted compound (mycotoxins and residual solvents)
    - A laboratory must provide the equation and the type of curve fit used for the calibration range, and the percent relative standard deviation or the goodness of fit

- **Demonstration of Method Accuracy and Precision:**
  - A laboratory must supply the quantitation data for five positive control samples analyzed by its testing method
- **Demonstration of Method Detection Limit**
  - A laboratory must supply the quantitation data of seven low-level positive control samples
  - The concentration of these low-level positive control samples is set equal to the lowest calibration point the laboratory uses
- **Demonstration of Low System Background**
  - A laboratory must supply the analytical data of at least three negative control samples that do not contain any mycotoxins, residual solvents, or cannabinoids
- **Demonstration of Analyte Identification**
  - A laboratory that uses HPLC, GC-FID, or GC-PID/FID instrumentation must supply analytical data where each targeted compound is analyzed as a single compound giving its characteristic retention time

- **Laboratory data reporting**
  - All certificates of analysis (lab reports) will require a batch number or code issued by the state-approved seed to sale inventory tracking system;
  - Corrective action report (CAR) required if test results are incorrect or have been altered

- **Approved destruction methods:**
  - Waste must be rendered unrecognizable, mixed with 50% non-cannabis waste
  - Compostable vs non-compostable
  - May be done at NMED certified composting facility, or done on site if property is owned by licensee
  - Hazardous vs non-hazardous waste designation
  - Lighting waste included
  - Documentation required
  - Track and trace methods
  - Notification to department

- **Certified calibration of all balances (scales) used in the production, distribution, and manufacturing of usable cannabis products**

We support and currently comply will all above general provisions.

Respectfully submitted,

Kathleen O'Dea
Director – Scepter Lab

Barry Dungan

October 4, 2019

Rio Grande Analytics, LLC

My name is Barry Dungan and I am a co-owner of Rio Grande Analytics. As a licensed medical cannabis laboratory owner/operator I have years of hands on experience performing the tests highlighted below. The additional tests proposed in the rule change are incredibly important in protecting public health but considerations must be given to laboratories to accommodate these requirements while continuing to serve an expanding number of patients. Please understand that not only will laboratories incur extreme expenses to acquire new machinery and expand their testing facilities, they will also need to comply with other industry standards regarding hazardous materials, employee training and protection, and waste disposal. I am concerned that without sufficient time and planning, laboratories may not be able to purchase and establish the equipment and protocols necessary to comply with new regulations.

The implementation of pesticide and heavy metal testing will have a significant impact on all laboratories in New Mexico. Pesticide and heavy-metal testing, done properly, will require three separate machines, GC-MS, LC-MS, and ICP-MS, each of which are several hundred-thousand-dollar investments. Not only will laboratories need new equipment and waste removal systems, they will also need highly-trained personnel to operate and maintain machinery.

Therefore, I propose that new regulations be prioritized and implemented incrementally in two separate phases. Pesticide testing is the most important test not currently required by the New Mexico cannabis program and should be implemented first as it poses the greatest hazard to patient health. Establishing heavy-metal testing, and possibly expanding mycotoxin and pesticide detection lists should be completed in phase two, after reliable pesticide testing has been properly established.

I would like to suggest the timeline below as a start to the discussion on how to move forward and provide the best and most necessary information to patients in the medical cannabis program as well as other industry stakeholders. The outline below is an attempt to arrive at a timeline for implementation that is feasible and best serves all participants and providers in the program. I have also added suggestions to the Proposed Rule Change Summary to address concerns outside of the timeline for meeting new regulations.

Phase 1: (January 2021) All of the changes in this proposed rule, excluding heavy metals

We are currently in compliance with all DOH requirements and those in the proposed list with the exception of pesticide and heavy metal testing. Although I agree with the need and the importance of adding these tests, they will come with a tremendous financial burden as well as a training curve for additional skilled employees. Addressing new regulations individually will enable laboratories to successfully comply with new regulations and manage their associated expenses. We are committed to providing these services, but need time to do so accurately and reliably. It will take no less than 6 weeks from the order date to receive and install the equipment required for pesticide testing alone. If the equipment were to be ordered today, it may not be ready until the first quarter of 2020.

Phase 2: (January 2022) Heavy Metals

Because analysis of heavy metal contamination comes with other waste streams and environmental impacts, I feel this will be better coming online in phase 2 for reasons that are mentioned below. Again, with this instrumentation, there will be at least a 6 week lead time after purchasing and will require a $250k investment. Also, personnel will need to be identified and trained and the disposal of waste and employee protection will need to be addressed. These are all manageable, but require time and money to establish. This test can come with a possible increase to pesticide testing in year 2. It is possible that there will be other compounds of interest to test for in a year or 2 and they can be added at an appropriate time. Examples are synthetic cannabinoids, more mycotoxins, tocopherols (vitamin E), other vape contaminants. There may also be a need for new microbial panels to be added. Time will allow us to generate data and implement tests that increase public health and safety.

PROPOSED RULE CHANGE SUMMARY-WORKING DRAFT NOT FINALIZED

- **Quality Assurance testing**- Random testing of products at Departments discretion

  I agree that some type of secret shopper system should be in place to determine that the products are labeled properly and that the results for each product are available on demand. I believe that this is already in place, but I am unaware of the consequences of failure or the incentives for compliance as it is out of our perview. I can tell you that I get calls weekly from patients asking for results from products they have purchased, that don't seem to be available from the purchase source. They want answers. The test results are only partially represented and almost impossible to read on the final packaging. In a grocery setting, the labels alone would never pass compliance. We have and always will send a COA for any sample processed in our facility to the producer requesting testing services.

- **Mycotoxin testing**
  - Testing laboratories will utilize HPLC, LCMS, or LCMSMS instrumentation for the testing of mycotoxins
  - A laboratory will use no more than two significant figures to report a positive mycotoxin result
  - A laboratory will report a non-detect of a mycotoxin as less than the laboratory minimum reporting level
  - The laboratory's minimum reporting level must be equal to or less than 1 µg/kg
  - A laboratory will also report a PASS or FAIL evaluation with the reported result
  - Rio Grande Analytics currently has this in place. We use an HPLC with a post column derivatization box and a fluorescence detector for the detection and quantification of mycotoxins. I think that it is valuable to be able to separate the

compounds of interest and quantify them individually. We are in the process of upgrading to UPLC/MS/MS to further confirm the presence or absence of the mycotoxins currently required (G1, G2, B1, B2, OTA). This will also allow us to structurally identify each compound to rule out false positives and allow us to expand the list of toxins as the program needs increase. This will also allow for the simultaneous detection of pesticides. More in that section below.

- **Heavy Metal testing will be required on all usable cannabis:**

Table 5. New Mexico Department of Health Medical Cannabis Program
Heavy Metal Testing Requirements

Heavy Metals	Elemental Symbol	IUPAC Name	CAS Number	Action Level (µg/g) or (ppm)*	Method Reporting Level (µg/g) or (ppm)*
Arsenic	As	arsenic	7440-38-2	2.0	1.0
Cadmium	Cd	cadmium	7440-43-9	0.8	0.2
Lead	Pb	lead	7439-92-1	1.2	0.2
Mercury	Hg	mercury	7439-97-6	0.4	0.1

*Micrograms per gram (µg/g) of sample is equivalent to parts per million (ppm).

This test is going to be the most difficult to get online in my opinion. The technique most likely to do the job will be and ICP-MS (Inductively Coupled Plasma-Mass Spectrometry). While I do agree that this test should be done, it will come at a huge cost to labs, producers and ultimately passed on to consumers. This will require a $250k investment to acquire the needed instrumentation. Personnel will need to be identified and trained. These are delicate instruments that require constant maintenance. If an instrument goes down, it can take days and sometimes weeks to order and obtain parts. It is too expensive to keep an extra ICP in house for unexpected instrument issues. The sample preparation for this technique includes dissolving the sample in nitric acid and placing it in a microwave digester. The waste stream associated with this test also presents disposal issues that have not yet been encountered in the program. This is just something to keep in mind in the decision-making process when asking the labs to rapidly adhere to changing regulations. I am committed to providing these services, but you should be aware that some consideration should be given to allow remediation of certain problems that will unfortunately occur. I believe it would be best to introduce this test after the pesticide rule goes into effect to allow labs to take these new regulations in phases. This test should be phase 2 in my opinion.

- **Pesticide testing on dried usable cannabis (i.e. flower, shake trim etc.)**
  - Testing laboratories will utilize HPLC, LCMS, or LCMSMS instrumentation for the testing of pesticides.
  - A laboratory will use no more than two significant figures to report a positive pesticide result.
  - A laboratory will report a non-detect of a pesticide as less than the laboratory's minimum reporting level.

- The laboratory's minimum reporting level must be equal to or less than 100 µg/kg.
- A laboratory will also report a PASS or FAIL evaluation with the reported result.
- This is a step in the right direction for the immediate safety of the patients in the Medical Cannabis program. I think this should be the main focus of a phase 1 update to the testing requirements. It is widely known that pesticides are harmful compounds and a basic list is a good start. It is very difficult to make a list, because it gives people something to avoid. The instrumentation required to do this test will not only detect the compounds on the list, we will be able to flag samples that have suspicious contaminants for further analysis. It will also allow laboratories to confirm the current list of mycotoxins and expand when necessary. Pesticide testing is a difficult test to perform and a delicate piece of instrumentation to constantly maintain to accurately report the data collected. Bringing this test online in phase 1 will allow labs to accurately report on pesticides and not become overburdened with financing and training heavy metals simultaneously. Pesticide testing will also require a large financial investment to acquire the needed instrumentation and personnel. I am committed to provide these services but will need time to get them in place. For clarification in the list below, do the isomers listed need to be separated and quantified independently? If so, is the reporting level 100ppb for each or as a total?

Table 6. New Mexico Department of Health Medical Cannabis Program Pesticides Testing Requirements

Targeted Pesticide	Common Chemical Name	CAS Number	Action Level (µg/kg)	Method Reporting Level (µg/kg)
Abamectin	avermectin B1a & avermectin B1b	71751-41-2	500	100
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Etoxazole	etoxazole	153233-91-1	200	100
Imazalil	chloramizole	35554-44-0	200	100
Imidacloprid	imidacloprid	138261-41-3	400	100
Malathion	malathion	121-75-5	200	100
Myclobutanil	myclobutanil	88671-89-0	200	100
Permethrins	*cis*-permethrin & *trans*-permethrin	52645-53-1	200	100
Spinosad	spinosyn A & spinosyn D	168316-95-8	200	100
Spiromesifen	spiromesifen	283594-90-1	200	100
Spirotetramat	spirotetramat	203313-25-1	200	100
Tebuconazole	tebuconazole	80443-41-0	400	100

*Micrograms of pesticide per kilogram (µg/kg) of sample is equivalent to parts per billion (ppb).

- **End product testing**- required on all usable cannabis products:
  - Dried usable cannabis: Microbiological test, Potency test, Mycotoxin test, Pesticide test, Heavy metals test, and moisture content analysis.
  - Concentrated cannabis derived products: Microbiological test, Potency test, Mycotoxin test, Heavy metals test, and residual solvents test.

- Cannabis derived products: Microbiological test, Potency test, Heavy metals test, and Mycotoxin test.
- Homogeneity of potency for cannabis derived products

I agree with the end of product testing. I still feel that the metal analysis should be incorporated in phase 2. I suggest pesticide testing should be done on concentrated cannabis derived products because of the possibility of contamination during the extraction/concentration process and the nature of the mode of ingestion of these products i.e. vaping

- **Sample Size increase**- Based on recommendations from United States Pharmacopeia expert panel.
  - Dried usable cannabis: 25.5 grams / 5 lb batch = 1.0% of harvest.
  - Concentrated cannabis derived products: 23.0 grams or 23.5 grams / batch.
  - Cannabis derived products: 23.5 grams per batch

Table 7. New Mexico Department of Health Medical Cannabis Program Minimum Test Sample Size

Targeted Parameter	Sample Matrix	Analysis Platforms (Instrumentation Used by Lab)	Minimum Amount Required for Testing (grams)
Cannabis Potency	dried usable cannabis	HPLC, LCMS	1.0
	concentrate	HPLC, LCMS	1.0
	cannabis-derived products	HPLC, LCMS	1.0
Cannabis Moisture Content	dried usable cannabis	n/a	1.0
Mycotoxins	dried usable cannabis, concentrate, or cannabis derived products	HPLC, LCMS, LCMSMS	1.0
Residual Solvents	concentrate	GC-FID, GC-PID/FID	1.0
	concentrate	GCMS	0.5
	cannabis-derived products	GC-FID, GC-PID/FID	5.0
	cannabis-derived products	GCMS	1.0
Absence of Salmonella spp. & E. coli	dried usable cannabis, cannabis derived product	Culture, Biochemical, Antibody, or Nucleic Acid- based assays Must be Validated Microbiological Methodology such as FDA, USP, AOAC, or equilivant.	10.0
Total Aerobic Microbial Count Total Combined Yeast & Mold Count Bile-tolerant Gram-negative Bacteria Total Coliforms Count	dried usable cannabis, concentrate, or cannabis - derived products	Direct Culture, Indirect Culture, or non-Culture based. Must be Validated Microbiological Methodology such as FDA, USP, AOAC, or equilivant.	10.0
Pesticides	Dried usable cannabis	HPLC, LCMS, LCMSMS	2.0
Heavy Metals	dried usable cannabis, concentrate, cannabis derived product	ICP-MS, FIMS	0.5

Minimum Test Sample Size May Change if A Validated Method is Approved by NMDOH MCP

I have a few suggestions to provide from my experience testing in this program over the last few years. I suggest that potency analysis be done on either LC or GC. The same results can be obtained by both, and both serve different needs. Potency for products like smokable flower is best done on GC. This is because you can profile the terpenes and cannabinoids simultaneously. This tool allows you to give another important piece of information in a single run that cannot be achieved by LC. On the other hand, products like edibles are best run on the LC to determine the amount of the acid and neutral forms of the cannabinoids which could not be achieved on the GC. Running an LC also generates a large waste stream while GC does not. I suggest that the client be able to request which test they would like to provide to their clients based on the products they are selling and that the labs provide both services. Moisture content is just an overnight incubation and actually the first step of mycotoxin analysis. I agree it is good to provide moisture content. I agree 1 gram is plenty to do that test. For residual solvents, I do not see the need for mass spectrometry and agree that FID should be an accepted method of detection. For the microbial panels (Salmonella, E. coli, RAC, RYM, EB, EC) I feel the current amount of 1g is sufficient to do the test. We currently have to do very large dilutions to accurately count colonies on petrifilm. Adding more dilution steps will add a huge waste stream of plastic bottles that are really not necessary. This is just a suggestion from a waste stream perspective. If any panel requires more material, I feel it will be pesticide testing. In order to detect compounds at the action levels provided, I think 10g minimum, if not more, should be required for that test. After the first year, that amount could be reduced or increased when phase 2 metals comes online. As for heavy metals, in my experience at the University, 50-100mg will be enough for microwave digestion and subsequent ICP-MS analysis. Half a gram should be plenty if confirmation testing is required when phase 2 is ruled in.

7.34.4.15 DEPARTMENT-APPROVED TESTING LABORATORIES; GENERAL PROVISIONS:

- **An Initial Demonstration of Capability (IDC) includes the following elements for all required tests:**
  - **Demonstration of Method Calibration:**
    - Minimum of five calibration points consisting of five different concentration levels of target compounds
    - The calibration range must include a low calibration point equal to, or less, than the required Minimum Reporting Level for each targeted compound
    - The calibration range must include a calibration point equal to the Action Level for each targeted compound (mycotoxins and residual solvents)
    - A laboratory must provide the equation and the type of curve fit used for the calibration range, and the percent relative standard deviation or the goodness of fit
  - **Demonstration of Method Accuracy and Precision:**
    - A laboratory must supply the quantitation data for five positive control samples analyzed by its testing method
  - **Demonstration of Method Detection Limit**
    - A laboratory must supply the quantitation data of seven low-level positive control samples

- The concentration of these low-level positive control samples is set equal to the lowest calibration point the laboratory uses

- **Demonstration of Low System Background**
  - A laboratory must supply the analytical data of at least three negative control samples that do not contain any mycotoxins, residual solvents, or cannabinoids
- **Demonstration of Analyte Identification**
  - A laboratory that uses HPLC, GC-FID, or GC-PID/FID instrumentation must supply analytical data where each targeted compound is analyzed as a single compound giving its characteristic retention time

- **Laboratory data reporting**
  - All certificates of analysis (lab reports) will require a batch number or code issued by the state-approved seed to sale inventory tracking system;
  - Corrective action report (CAR) required if test results are incorrect or have been altered

- **Approved destruction methods:**
  - Waste must be rendered unrecognizable, mixed with 50% non-cannabis waste
  - Compostable vs non-compostable
  - May be done at NMED certified composting facility, or done on site if property is owned by licensee
  - Hazardous vs non-hazardous waste designation
  - Lighting waste included
  - Documentation required
  - Track and trace methods
  - Notification to department

I agree that a section for "Other methods may be approved as necessary" should be added for unexpected disposal needs that may arise that cannot be foreseen.

- **Certified calibration of all balances (scales) used in the production, distribution, and manufacturing of usable cannabis products**

This has always been a requirement and we have and continue to hold all calibration records.

Rio Grande Analytics views our relationship as a collaborative partnership for the protection of public health and safety. Our interest is to provide professional information that will bring credibility, education and confidence to end users who choose this treatment as an option to their individual unique circumstances.

Best Regards,
Barry Dungan
Senior Research Assistant
Co-Owner Rio Grande Analytics

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November 22, 2019

Ms. Andrea Sundberg
NM Department of Health
Medical Cannabis Program
P.O. Box 26110
Santa Fe, NM 87502-6110 *via email to MCP.comment@state.nm.us*

Comments on Proposed regulations at 7.34.4 NMAC

Dear Ms. Sundberg:

This letter is filed as public comment in response to the Department's Notice of Public Hearing on the repeal and replacement of MCP rules at 7.34.2, 7.34.3, and 7.34.4 NMAC. These comments are based on the knowledge and experience gained through providing legal representation to more than one-quarter of all the entities holding medical cannabis production licenses, or their affiliates, to the largest medical cannabis testing laboratory in New Mexico, and to licensed manufacturers and patients.

Many of the Department's proposed revisions to the MCP rules are required by the 2019 amendments to the Lynn and Erin Compassionate Use Act (LECUA), or are otherwise good policy which continues the development of a program that puts a focus on providing patients with access to safe and effective medicine. Having supported and led state agency rulemakings myself, I understand and appreciate the level of effort by Department staff that went into creating the regulatory revisions that the Department now proposes. I also recognize that, in a welcome departure from past practices, the Department made some effort to consult with industry participants prior to publishing its final proposed rules. However, it appears that the Department did not bring an open mind to these limited consultations, and instead proceeded to publish its initial revisions without regard to feedback received. This is certainly the case as it concerns some of the testing requirements.

My specific comments follow:

1. **The Department May Not Reserve the Power to Promulgate Ad Hoc Rules**

The Department of Health may only promulgate rules affecting the entities it regulates by going through a formal rulemaking process with notice and comment, and publishing such rules in the Register and the Administrative Code. Yet, throughout the proposed 7.34.4 NMAC, the Department has purported to reserve to itself the power to create *ad hoc* regulations at its discretion, without going through notice and comment, or publication. This is not permitted by statute. The defective rules include (the following may not be an exhaustive list):

7.34.4.8(G)(4) "requiring additional information as the department deems necessary"[1]

7.34.4.8(O)(14) "such other policies or procedures as the department may require."

7.34.4.14(B)(25) "such other materials as the department may require."

7.34.4.17(D)(11) "such other materials as the department may require."

7.34.4.22(I)(3) ". . .such other information as the department may reasonably request."

7.34.4.26(B)(12) "such additional information or materials as the department may require."

7.34.4.29(B)(3)(r) "Such additional information as the department may request."

The Department of Health's organic act provides that: "Unless otherwise provided by statute, no rule affecting any person or agency outside the department shall be adopted, amended or repealed without a public hearing on the proposed action before the secretary or a hearing officer designated by him." NMSA 1978 9-7-6(C). "The statutory designation for an enactment by an agency designed to have the force and effect of law and to control the actions of persons who are being regulated by the agency is a 'rule'." *Bokum Res. Corp. v. N.M. Water Quality Control Comm'n*, 1979-NMSC-090, ¶ 41; see also NMSA 1978 14-4-2(C) ("rule" is any regulation or standard purporting to affect persons not employees of a state agency).

In each of the instances listed above, the Department purports to claim the ability to control the conduct of regulated entities using standards that it has not published in a formal regulation. That is improper. While all the examples provided above are defective, the most egregious is 7.34.4.8(O)(14), by which the Department purports to reserve unlimited power to impose new regulations on LNPPs without going through rulemaking. These defective rules should be stricken, and the Department should promulgate regular and emergency rules, as needed, as regulatory concerns change.

2. The Department May Not Restrict Producers to Non-Profit Corporations

The LECUA, as amended by SB 406, authorizes the Department to license "cannabis producers." NMSA § 26-2B-3(G). A cannabis producer is "a person that is licensed by the department to possess, produce, dispense, distribute and manufacture cannabis and cannabis products and sell wholesale or by direct sale to qualified patients and primary caregivers." *Id.* (emphasis added). Elsewhere, the Legislature directed the Department

[1] I recommend that subpart G be replaced with "The department may verify information contained in each application and accompanying documentation by requiring supporting documentation or other reasonable means" and striking the subparts" and striking the numbered subparts. The department obviously needs the ability to verify information, but (G)(4) opens the door to the Department unlawfully changing the application requirements .

to issue licenses to "(1) cannabis couriers; (2) cannabis manufacturers; (3) cannabis producers; (4) cannabis testing facilities; and (5) any other activity or person as deemed necessary by the department." NMSA § 26-2B-6.1(D). The Department mostly complies with this in its proposed regulations by providing for the licensure of "couriers," "manufacturers," and "laboratories," but the Department doesn't license "producers." Instead, the Department has created a category of licensure different from the statute, the "non-profit producer."

The Department, under the authority of Section 26-2B-6.1(D)(5) could create the non-profit producer category, but only as an alternative to a generic "producer," which must be an entity that is a legal "person" of any type. This is required by the Uniform Statute and Rule Construction Act, which provides that the word "person" when used in statute, such as in the LECUA definition of "cannabis producer" *supra*, means "an individual, corporation, business trust, estate, trust, partnership, limited liability company, association, joint venture or any legal or commercial entity." NMSA 1978 § 12-2A-3(E).

In addition to being contrary to the Department's statutory authority, restricting producers to non-profit corporations is arbitrary and unjustified. Operation of a medical cannabis producer compliant with the Department's regulatory standards requires substantial capital investments. Nonprofit entities are unable to obtain capital as equity investments. The bank that has single-handedly made it possible for New Mexico cannabis businesses to have access to depository banking services since 2015 does not issue commercial loans to medical cannabis businesses. The ability of medical cannabis producers to obtain debt financing from private persons and entities who are related parties is very limited, and comes at a high cost.

In response to the Department's *ultra vires* and poorly conceived policy restricting producer licenses to nonprofit entities, for-profit affiliates of LNPPs have proliferated as a means of generating investment capital and incentivizing cost-effective operations. The economic effects of such affiliations are, in many cases, almost the same as if the license was held by a for-profit, but with a loss of transparency and diminished accountability. The Department is well aware of these arrangements, and routinely approves (or passes) on them. The Department's proposed regulations evidence the confusion, referring in places to the "owners" of nonprofit producers. Further, as the Department is aware, LNPPs receive none of the tax benefits of non-profit status.

For the preceding reasons, the Department should eliminate the restriction of producer licenses to non-profits and permit existing license holders to transfer licenses to their existing affiliates.

3. Application of the Three-Hundred Foot Limit Must Comport to Statute

The Legislature prohibited cannabis distribution activities within 300' of a school, church, or daycare center. NMSA § 26-2B-7(A)(6)(b). The Legislature did not extend the 300' requirement to production facilities, or for that matter to laboratories or manufacturers. For production facilities, the Legislature specified instead that they be on

"secured grounds." NMSA § 26-2B-7(A)(6)(a). Under the well known canon that, when the Legislature shows it knows how to enact a provision in one circumstance, but does not do so in another, legislative intent is that the Legislature did not intend that provision to apply where it was not specified.

Moreover, there are obvious reasons why the Legislature could have wanted to put a buffer between school children and preschoolers and the very public activities of retail cannabis distribution. There is no obvious or even plausible reason why production activities, which are not visible to persons outside of the building in which they are housed, would need to be placed a distance from schools and churches. The Department should change 7.34.4.8(F) to only apply the 300' restriction to producers' distribution facilities, to be consistent with statute, and remove it from .9(A) 5, .14(B)(8), .15(A)(5), and .17(C)(18).

Next, the Legislature amended the LECUA in 2019 with SB 406 to address the situation in which a cannabis facility is compliant when it is first opened and approved, but subsequently a school or church moves into the 300' radius, by adding the underlined words:

> distribution of cannabis to qualified patients or their primary caregivers to take place at locations that are designated by the department and that are not within three hundred feet of any school, church or daycare center <u>that were in existence in that location before the licensee distributing medical cannabis nearby was licensed</u>;

The Department must add these underlined words to 7.34.4.8(F). If the Department does not remove the 300' restriction from the production, manufacturing, and laboratory rules to comport with the Legislative intent that the 300' limit only applies to cannabis distribution, it must add the above-underlined words to the respective rules to be in partial compliance with statute.

4. Standards Necessitating License Amendment are Over-Broad

The proposed regulations at 7.34.4.8(R)(2) and .17(J)(1) require application license amendment by a producer or laboratory upon "any physical modification or addition to the facility." This is an arbitrary and over-broad standard bearing no relation to any legitimate regulatory concerns. Under the plain language of the regulation, a licensee would be required to go through a costly and time-consuming amendment process any time it adds lighting, changes flooring or surfaces, reconfigures a back office or break room, or makes any number of possible physical modifications that have no effect on security or other regulatory concerns. These regulations should be re-written to require amendment only for physical modifications that add or removes space to areas where cannabis is dispensed, stored, or produced; or that change the location of external doors; or which materially changes the security system.

The proposed regulations at 7.34.4.8(R)(2) and .17(J) also require amendment upon the change in ownership of facilities. Transfers in building ownership by the third-party, arms-length landlord of a cannabis business has no regulatory import and should not require a filing by the business. This requirement appears to come from the Department's concerns about disclosure of the identity of related parties to cannabis businesses. The Department should make a related party rule to focus on the circumstances with which it actually interested, and eliminate rules like these that burden licensees engaged in standard business practices with arms-length third parties. Similarly, licensees should not be required to disclose all persons with indirect interest in facility ownership, whose identities may not be known to them in the context of an arms-length lease.

The proposed regulations at 7.34.4.8(R)(2) requiring amendment for changes in LNPP directors is also excessive and burdensome to the ordinary course of business for LNPPs, in which directors resign without notice or must be replaced immediately for other reasons. Moreover, other rules already require background checks and issuance of an employee card for new directors. The Department's additional needs to know about director changes could be satisfied by a notice requirement.

5. Issues with Laboratory Testing Requirements

a. Rules specifying when testing is required are ambiguous, and unworkable.
Proposed rule 7.34.4.10 appears to require testing before any transfers of cannabis can occur. It expressly requires testing of dried cannabis before it is manufactured into a CDP. It is wasteful and to no benefit to require testing of dried cannabis (either flowers or trim) which is destined for extraction. The regulatory needs are met by testing the extract or other resulting CDPs prior to their being released for distribution to patients. This rule should be rewritten to require testing before any distribution of cannabis of CDPs to patients, and otherwise permit licensees to transfer untested cannabis on a wholesale basis between themselves, if they so desire, and to not test dried cannabis that will be used to make an extract.

b. Microbiological Testing Requirements/Action Levels are Excessive
The Department has specified action levels for microbiologicals that exceed what some other states require. Over-regulation in microbiological testing adds unnecessary costs for production activities and remediation. Unnecessary remediation can also adversely impact cannabis medicine.

The recommendations from the Cannabis Safety Institute white paper should be adopted, which also comport with the extensive experience of Scepter with respect to samples which have failed microbiological screening, for which the lab often engages in follow-up investigations:

1. Cannabis should be tested for four species of Aspergillus: A. flavus, A. fumigatus, A. niger and A. terreus. Together these species are responsible

for the vast majority of cases of invasive pulmonary aspergllosis and they are the only pathogens that represent a clear and certain danger on cannabis.

2. Cannabis should be tested for total generic E. coli. Samples with levels above 100 cfu/gram should be rejected. This is the one indicator test that we recommend. Detection of significant levels of E. coli are strong evidence of problems during growing or processing. E. coli is now accepted to be the optimal indicator organism for the identification of possible fecal contamination. Were pathogenic bacteria to be present, they would likely have arrived through this type of pathway, therefore samples positive for E. coli are indicative of general production problems that need to be addressed.

3. Cannabis should be tested for Salmonella. The odds of salmonella infection from cannabis are very low. Nonetheless, it is the one bacterial pathogen that poses a potential threat to cannabis smokers. There is precedent for salmonella association with cannabis. It is highly infectious and can cause disease with as low a dose as one single cell. It is hardy and resistant to dessication.

4. Testing cannabis for total yeast and mold is unnecessary and unjustified. Total yeast and mold tests detect only a small fraction of the fungal species in the environment, and do not correlate with the presence of pathogenic species. The only pathogenic mold species on Cannabis are types of Aspergillus that should be tested for separately. Molds can potentially be a cause of allergic hypersensitivity reactions, but there is no evidence that these are mediated by smoking. In the alternative, the combined total yeast and mold count action level should be relaxed, as it is not indicative of health risks, and is often triggered by the presence of benign yeasts.

c. Routine Mycotoxin Testing Should be Eliminated

As of this fall, Scepter Lab had conducted 15,649 mycotoxin tests on medical cannabis samples since the requirement was implemented in NM, at a cost to producers of $704,205,00, without registering a single positive result. To our knowledge, there has not been a single positive mycotoxin test result by any NM cannabis laboratory. Confident Cannabis, a company providing a popular cannabis laboratory software platform, says its records only show about 100 positive results for mycotoxins across all of its client laboratories, and none arising from activities in dry climates like ours. Confident Cannabis states that it has a 40% market share of labs across the U.S. and Canada.

Kathleen O'Dea, who has advanced credentials in microbiology and has worked in microbiology outside the cannabis industry as well as operating Scepter, has reviewed the scientific literature and concluded that mycotoxins are rarely found in cannabis because

the material does not support the growth of the organisms that produce mycotoxins or the production of mycotoxins. The Cannabis Safety Institute states that "seedless cannabis plants are not capable of supporting aflatoxin production, because they lack the high oil content necessary for replication."

Moreover, The Cannabis Safety Institute also finds that "Aflatoxins will degrade by the heat of smoking or decarboxylation, if any were present."

Thus, a requirement for routine mycotoxin testing, at very material expense, is arbitrary and capricious and not supported by any reasonable assessment of risks.

d. Routine Heavy Metal Testing is Unjustified

The Cannabis Safety Institute only recommends heavy metal testing where cannabis is grown outdoors on land where there has been historical use of arsenic based pesticides that has accumulated in the soil. (Arsenic-based pesticides are today banned in the U.S.)

To my knowledge, all medical cannabis cultivated indoors in our state is grown in media obtained or produced from commercial products marketed for this purpose. All of the medical cannabis I have seen being grown outdoors in New Mexico has also been grown in such media, in containers, and not in the native soil. The MCP, which has visited all outdoor production sites, can verify that cannabis is rarely, if ever, grown in native soil better than I.

It is not possible for cannabis grown in commercial growing media to become contaminated with heavy metals. It is arbitrary and unjustified for the Department to require routine heavy metal testing , which will impose very significant expenses on the testing laboratories and on the producers, in the absence of any plausible risk. Scepter estimates the cost of the equipment necessary to implement heavy metal testing will be well in excess of $100,000 to purchase or at least $30,000/mo to lease.

A reasonable rule that protects patients from heavy metal-contaminated medicine would target soil, not the cannabis. The Department could (and should) require any producer proposing to grow in native soil to have that soil tested for heavy metals before the production area is licensed. Such testing, since it would not involve any cannabis, could be provided by any nationally accredited laboratory.

e. Pesticide Testing Should be Refined

The Departments regulations permit the use of any licensed pesticide, but require testing for only 13 substances. This is both too many and too few. Too many, when it is wasteful to require testing for substances that have not been used in the cultivation of a particular batch of cannabis, and too few, when the rules allow the use of substances that will not be tested for. The Department is justified in seeking to prevent patients from being exposed to pesticide residues, but the proposed rules are not well-tailored to this end.

In addition, the equipment and supplies to implement pesticide testing are expensive to obtain. The list price for the equipment is $450,000. It is not possible to economically amortize an upfront cost like that over the volume of testing samples in New Mexico. Scepter estimates it will need to charge $250 per sample for pesticide testing.

The Department should withdraw the pesticide testing rule and convene a work group of patients, producers, and testing laboratories to arrive at a workable rule.

f. Requiring Specific Testing Technologies and Samples is Unjustified

The proposed rules mandate that laboratories use certain technologies for required tests (Table 7). This is arbitrary and unjustified. The Department has a legitimate regulatory interest in assuring that testing is performed accurately. But laboratories should be permitted to utilize any technology that can demonstrate sufficient testing accuracy. By mandating specific technologies, the Department may require a laboratory to incur unnecessary costs to replace equipment that is functional, and will certainly discourage innovation that can lead to greater testing efficiency.

In a specific example of how this mandate is unjustified, Scepter currently uses the ELISA method for detecting mycotoxins. This method is fully validated for use in cannabis and generates numerical data that "matches" with HPLC. Scepter has been validated by NMDOH and its Scientific Laboratories Division as being capable of producing accurate results in mycotoxin testing using its current method. Other states allow the ELISA method.

The first steps in the ELISA method are procedurally identical to the HPLC method. The only difference is how the active material is "read" - HPLC or spectrophotometer. From interaction with DOH's Scientific Laboratories Division, Scepter knows that it prefers the HPLC, but there is nothing "wrong" or "invalid" with the ELISA method. It would be a significant hardship and expense for Scepter replace its spectrophotometers with a new detector for its HPLC machine, and it would take months of validation studies to bring this on-line. Mandating certain methods and rejecting others which are completely functionally equivalent is the textbook definition of "arbitrary" government conduct.

Next, the Department should also not mandate specific sample quantities in rule. There is no plausible reason for doing so. Sample sizes should be what is determined by the testing laboratory to be necessary for it to provide complete and reliable results. Any amount in excess of this is effectively an unnecessary expense to producers, and serves to increase the cost of medicine to patients. Mandating excess sample sizes, like all regulations that increase testing costs, incentivizes producers to find ways to test less, which is ultimately contrary to the objectives for the testing regulations.

g. "Quality Assurance Testing" is of Limited Value

The Department proposes to test, or obtain tests of, cannabis and CDPs it obtains from producers and manufacturers in 7.34.4.12. The results of such testing are not indicative of the testing accuracy of laboratories which may have tested a sample from the batch

which is now being examined by the Department, nor are such results indicative of anything other than how that singular, individual product tests. Cannabis is biological material and will differ by as much as 30% from the top of the plant to the bottom or from plant to plant. That portions of a harvest may be exposed to different conditions during drying, curing, and other processing also introduces non-uniformity.

h. End Product Testing is Unjustified

The Cannabis Safety Institute recommends against end-product testing of cannabis edibles (food products), and recommends instead requiring production under sanitary conditions, which the Department elsewhere does in its rules. *Microbiological Safety Testing of Cannabis*, Cannabis Safety Institute, May 2015. This approach follows the best practices in the production of commercial foodstuffs. Cannabis Safety Institute states:

> Cannabis food products are as likely to become contaminated as any other processed or prepared commercial food product. But because of its unique attributes, Cannabis is the least likely component to be the source of contamination in any food product. [emphasis in the original.] Cannabis is present in foods as an extract of the plant material. This plant material is dried to a safe level before extraction. And then either during or after extraction it is usually subject to a decarboxylation process that serves as a heat-kill step. The vast majority of the extraction processes are themselves sterilizing. Once these extracts are added to food, the food can always be mishandled or subject to "temperature abuse", which raises the chances of contamination. But these are factors facing all foods, and the only pathogen of real concern on Cannabis (Aspergillus) is not infectious by the oral route. Cannabis food products should be regulated as all food products are . . .

i. Repeat "Initial Demonstrations of Capability" are Unjustified

The proposed rules at 7.34.4.19(F) require an Initial Demonstration of Capability (IDC) whenever a laboratory is initially approved for a platform, or when equipment is moved, or a new instrument installed. The rules at 7.34.4.17(C)(17) require documentation of IDCs to be provided with renewal examinations. This specific rule should be eliminated, as there is no benefit to requiring the resubmission of documentation for a previous IDC with renewal, assuming that this rule is requesting resubmittal. If it is requesting a new IDC, that is not only inconsistent with the IDC rules at 7.34.4.19(F), it is arbitrary and unjustified.

"Initial Demonstration of Capability" means just that – an initial demonstration. It is reasonable for NMDOH to require a laboratory to prove that it can perform testing using a particular platform with accuracy, and under a range of concentrations, prior to approving the lab for that platform. An IDC is a demonstration that a laboratory has the basic capabilities, which are testing machines and other equipment, consumables, and standard operating procedures, to test with accuracy using a platform. If the laboratory is not changing any of these parameters, then there is no reason to require another initial demonstration. In satisfying an IDC, a laboratory makes a focused effort to produce

specific demonstrations outside of its normal commercial operations. Thus, a redundant IDC has no real value in demonstrating the accuracy of a laboratory's routine operations. Scepter's experience, which comports with common sense, is that once a laboratory has developed the ability to satisfy an IDC requirement for a platform, it can always replicate that showing, given sufficient expenditure of time and money. Redundant IDC requirements are effectively a bunch of "busy work" providing a purely superficial appearance that the Department is assuring that a laboratory is maintaining operational accuracy.

For these reasons, it is also unjustified for the Department to require a new IDC whenever equipment is relocated. IDCs are expensive in time and materials. They primarily test procedures, which will not have changed with the movement of equipment. Concerns that testing machines may have been affected by the jostling of being moved between locations or by their position in the laboratory relative to other machines and HVAC can be addressed with much simpler and less costly confirmatory analyses.

6. Other Comments

7.34.4.7(F), definition of Applicant. This definition is only needed and used with respect to patients and caregivers. There is no need to include producer applicants in the definition, and it creates ambiguity.

7.34.4.7(R) and (T), definitions of diversion and inversion are over-broad, and make the definitions less useful, and potentially subject to void for vagueness challenges if any transfer of cannabis that is unlawful; i.e., in violation of any rules, is a diversion/inversion. The Department should narrow these definitions to pertain to transfers from or to persons who are not licensed entities.

7.34.4.7(EE). For some time, the Department has used "Director" as the title of the person who administers the program, the rules should be consistent.

7.34.4.7(FF). The LECUA requires that the Department issue patient registrations upon a practitioner's certification; it would be unlawful for the medical director to exercise the power provided in this definition.

7.34.4.7(NN). It exceeds statutory authority for the Department to exclude petitions for covered conditions from persons who are not residents.

7.34.4.8(A)(2) and (K). The Department reasonably licenses multiple production facilities under a single license. Concurrent operation of an indoor and an outdoor grow is common in the program, and is desirable for allowing producers to produce medicine to meet patient needs year-round, at the lowest cost. The rules at .8(A)(2) should state "one or more facilities" and not imply a restriction to "a facility" for clearness. In addition, at subpart K, the rules should not restrict production to one facility, nor allow facilities at the Departments arbitrary "discretion." .8(A)(2) should be rewritten to state "A producer shall conduct its operations only at the physical locations approved by the

department, which facilities shall be reasonably necessary to supply the cannabis needs of the patients served by the producers, and whose numbers and locations shall not unreasonably burden the department's ability to monitor production activities."

Thank you for your attention to these comments.

Sincerely,

Jason Marks

Gmail by Google

Kathleen ODea <kkodea@scepterlabs.com>

Mycotoxins and Metals

1 message

Tony Lewis <tony.lewis@kassenco.com> Mon, Nov 11, 2019 at 6:27 PM
To: Kathleen ODea <kkodea@scepterlabs.com>

Hi Kathleen,
Some numbers as promised. Note that these are large datasets and I haven't investigated individual failures, simply taking the lab result data as I see it. Its also worth noting that "failures" are defined within each state so could be different thresholds

Mycotoxins
- We have seen 70k tests for indoor flower with 75 fails = 0.11%
- 1.2k tests for outdoor flower with 26 fails = 2.15%
- Overall 0.14% fail rate

Metals
- We have seen 50k tests for indoor flower with 209 fails = 0.41%
- 1.1k tests for outdoor flower with 60 fails = 5.48%
- Overall 0.52% fail rate

Much higher failure rates for outdoor but also much smaller sample sizes. Indoor fower failure rates are also trivially low

Hope this is helpful!

Best
Tony

PC 2019-02-11

New Mexico Department of Health
Medical Cannabis Program

Public Meeting 11/22/19

Written Comments from Minerva Canna, Inc.

1. I thank the committee for the opportunity to summit these written comments of our concerns related to the proposed new testing requirements. We take patient safety in the consumption of cannabis products very seriously and whole heartily agree in the need for adequate testing requirement. Minerva was one of the first, if not the first NM company to incorporate regular testing into our production and manufacturing practices, long before it was a requirement from the DoH.

2. **COSTS:**
   Minerva is and always has been very concerned with patient safety and dedicated to providing patients with safe, clean, quality medicine at the lowest possible cost. We support to some degree the need for additional testing for pesticides and heavy metals, however, the frequency of these tests are unnecessary, and financially burdensome. These proposed additional testing requirements carry substantial associated costs estimated as much as $700.00 per 5lb batch of flower. These additional costs will undoubtedly be passed on to the price of the end product.

3. **HEAVY METALS:**
   LNPP's do not regularly change their growing processes that they've developed over long periods of time. Once they successfully establish a growing program, they stay with it and fine tune it. These practices include the type of soil or soilless medium used, types fertilizers used, water, the source of that water, the management of pest etc. If an LNPP passes a heavy metal test with their growing processes in place, it's a given that they will continue to pass the same test in the future with all things remaining constant. Therefore, I recommend that a heavy metal test be performed bi-annually to assure that heavy metal continue to be absent from the LNPP grow operation rather than the proposed testing of every batch. If an LNPP fails a heavy metal test, I recommend they be tested monthly until they pass three continuous tests, then tested bi-annually.

4. **PESTICIDES:**
   It is understandable why the Medical Cannabis will not publish a list of acceptable pesticides for use on cannabis. There are many factors that affect the successful use of pesticide on cannabis, such factor as; frequency of use, type of application, timing of application, and stage of plant growth during application. Historically other states that have published lists of acceptable pesticides have been besieged with problems. Because of this I do not recommend that the NM DoH publish a list of acceptable pesticides for use in cannabis productions.

All LNPP's should follow safe principles when using pesticides. They should only use pesticides that are recommended for cannabis, they should be organic in composition and they are applied according to labeling recommendations, however, some LNPP's may violate these principles and testing should be required.

Because of the way cannabis is grown by LNPP's in NM, mainly because of our limited allowable plant count, many different strains are grown in the same room. If an insect infestation invades one plant, it invades the entire room. The insect eradication efforts therefore would be to treat the entire room equally rather than one specific plant. It would stand to reason that if one plant tested positive to the presence of pesticides, then the entire crop would likewise test positive, conversely, if plants test negative to the presence of pesticide, then the entire crop would likewise test negative.

I have two recommendations for testing for the presence of pesticides

1. Test one strain of each harvest of each room.
2. Random spot samples chosen by a DoH represented on an unannounced inspection for pesticide testing.

5. **EDIBLES:**

Edibles production in the NM cannabis industry is manufactured in small batches, example 70 brownies at a time or 100 chocolate bars. It would be cost prohibited to test every batch produced, that stringent of testing requirement would destroy the edible market in NM. Currently the testing requirement is to test the concentrated distillate oil that is to be used to manufacture the edibles. This practice works well because if the oil tests successfully then the edible too would test successfully from micro toxins, heavy metals and the presence of pesticides. However, this does not ensure that an edible could not test positively for some other type of impurity acquired in the manufacturing process. Because of the sheer volume of various types of edible produced it would be cost prohibited to test each batch but not so cost prohibited to test a small percentage of edibles produce from each batch of oil.

For example, if a batch of distillate oil was to be established at 2000 mgs., and that batch of oil was to produce:

500 brownies = 14 sheets (2 days of production)
500 lemon bars = 14 sheets (2 days of production)
2000 gummy bears = 2 production runs. 4 production runs can be performed daily
200 chocolate bars (400 chocolate bars can be made daily)
600 cookies

A reasonable testing sample could be .001% of each different item produced from the original batch but not redundancy in testing for pesticides or heavy metals because that test was already preformed on the distillate oil.

With the above quantities and testing requirements at .001% we would be testing the following out of every 2000 mg. batch of oil:

1 brownie
1 lemon bar
2 gummy bears
1 chocolate bar
1 cookie

If the additional test was to cost $150 each, that add $750 to the cost of the products divided accordingly, in addition to the original cost of the oil. If the proposal to test every oil batch to the full battery of test at an estimated cost of $700.00 the new testing requirements would add approximately $1450.00 to the cost of those edibles listed.

In summary, we support additional testing of cannabis products available to the patients of New Mexico to assure them that they are purchasing clean, safe, quality medicine. Minerva strives to provide safe, quality medicine at the lowest possible cost. However, these proposed additional testing requirements would add substantial cost to every product produced, they are unnecessary redundant in nature, and needlessly burdensome to the operation of providing safe medicine to NM patients. We need to work together to find a compromise of insuring NM cannabis patients are receiving the safest medicine possible without strangling LNPP's with extraordinary testing costs that will ultimately be passed on to the price of the medicine. Minerva wants the price of medicine to be more affordable to NM patients so that they stay in the program, are able afford the medicine they need and, in the quantities, necessary for them to maintain their health and wellbeing. Let's be responsible in these testing requirements; but let us also be reasonable.

Respectfully submitted,

Erik Briones
President, Minerva Canna, Inc.

[EXT]

Brooke Duverger <naturalrxnm@yahoo.com>

Fri 11/22/2019 9:57 AM

To: comment, MCP, DOH <MCP.Comment@state.nm.us>;

1 attachment

Natural Rx Comments on Proposed Regulatory Changes - 11.22.19.pdf;

Attached are Natural Rx's comments regarding the proposed medical cannabis regulations.

Thank you

Brooke Duverger

November 22, 2019

Andrea Sundberg
NM Department of Health
Medical Cannabis Program
P.O. Box 26110
Santa Fe, NM 87502-6110
MCP.comment@state.nm.us

Re: Comments on Proposed Rules NMAC 7.34.4; Public Hearing November 22, 2019

To Whom It May Concern:

Natural Rx respectfully submits the following comments regarding the Department of Health's Medical Cannabis Program rules, which are to be considered at a public hearing scheduled for November 22, 2019.

Natural Rx believes that implementing common-sense testing and labeling requirements for medical cannabis is in the interest of public safety, protects the integrity of the program, and is generally the right thing to do. With that, some of the regulations proposed by the Department of Health are quite onerous, may not be feasible for existing labs, and will likely increase costs to patients. This may in turn have the opposite of the intended effect by pushing patients to the illicit market where products have no testing requirements and could make them sick. Below we will discuss our questions and concerns regarding these proposed regulations in the hopes that it will help inform the Department as it continues to refine them.

7.34.4.9 (2) – ***"all equipment, implements, and fixtures shall be used exclusively for the production of cannabis".*** This is concerning as there are many items in our facilities that are not used solely for that purpose, including computers, equipment in employee break rooms, and other items commonly found in the workplace. We would recommend revising this allow for such items.

7.34.4.9 (4) – ***"that production is conducted in a manner that does not allow cross-contamination from chemical or biological hazards".*** While this is a goal that we support, it is unclear what would be considered "chemical or biological hazards" under this regulation. We would recommend including a definition to ensure proper compliance.

7.34.4.9 (12) – ***"floors, walls, ceilings are constructed in such a manner that they are washable, wipeable, and non-absorbent, and kept clean, and kept in good repair".*** Natural Rx

is committed to ensuring all our facilities are clean and well-kept in the interest of safety for our employees and patients; however, this regulation seems more well-suited for a manufacturing facility than one for cultivation. Many cultivation sites are outdoors or are set up in a way that the floors, walls, and ceilings cannot be washed or wiped. We would recommend applying this regulation solely to manufacturing licenses.

7.34.4.10 – *Testing*. Natural Rx appreciates the staggered implementation to allow flexibility and time; however, we have several concerns about the feasibility of such regulations:

- Are the two labs currently licensed in New Mexico actually able to perform these tests?
- One lab is beyond a federal checkpoint that often results in the confiscation and destruction of cannabis, making its use unrealistic for operators on the other side of that checkpoint. Will one lab have the capacity to conduct increased sampling and testing?
- The samples and batch sizes are much too large, and it is unclear whether labs need to use that much.
- The sampling and random testing frequency is onerous and will result in a significant percentage of product being used for this purpose, which takes away from what we can provide to patients.
- Increasing the testing requirements drastically will result in increased costs to patients, which may be cost-prohibitive and lead to illicit market growth.
- The Department should consider alternative remediation options for flower.

7.34.4.11 (C) – *"waste shall be held in a secure designated holding area for a minimum of 72 hours prior to being wasted".* It is unclear what the Department means by "designated holding area". For example, can this be locked box or should it be a separate room on the premises? We would recommend adding a definition for this.

7.34.4.17 – *Labeling*. Natural Rx believes that the current proposed labeling requirements are unworkable for producers, particularly the 8-pt. font size as it will not allow enough room for all required information, and the Drug Information Sheets as they are duplicative and wasteful. We would recommend only having the THC and CBD content, testing data, warnings, and barcode on the product and requiring producers to have all other information readily available at the patient request.

7.34.4.27 – *Reciprocity*. Natural Rx is supportive of allowing reciprocity among other state medical cannabis programs as it will allow traveling patients to access the products they need; however, we would recommend providing more clarity on how this program will allow these patients to purchase from multiple producers as they are not required to obtain a New Mexico

medical cannabis card. It is currently unclear how this would work under the current BioTrack processes.

Natural Rx thanks the Department of Health and its staff for their hard work on drafting these regulations. It is no easy task to regulate an industry that has so much complexity, and we applaud New Mexico's leadership for making patient access a priority. If you have any questions regarding our positions, please contact Brooke Duverger at 505-235-1569.

Respectfully,

Brooke Duverger
General Manager, Natural Rx

PathogenDx
Setting the standard in DNA testing

January 2, 2020

Andrea Sundberg
NM Department of Health Medical Cannabis Program P.O. Box 26110
Santa Fe, NM 87502-6110

Dear Ms. Sundberg;

Please find PathogenDx Inc's response to New Mexico Regulations pertaining to the proposed rule revisions under 7.34.4 NMAC specifically related to:

- Section 7.34.4.10C(1) under Microbial testing

As of Dec. 27, 2019, 2,561 hospitalized vaping-related cases have been reported to the CDC; 55 people have died from the Vitamin-E Acetate crisis. Each of these cases resulted through the process of inhalation. What we put into our bodies and more importantly our lungs has a critical bearing on our health and safety, and we have painfully seen the consequences of this with national catastrophe impacting the well-being of consumers and patients in every state. Cannabis will continue to be inhaled whether medically or via adult-use.

As Cannabis is introduced for Medical purposes, potential microbial contamination becomes a major safety and health concern, in that many of the patients taking the drug may be immune compromised due to chemotherapy or age, in that the median age of therapeutic cannabis users is higher than that of the recreational market.

An understanding of the range of microbial contaminants in Cannabis has evolved rapidly in the past several years, due to seminal research papers by Thompson and colleagues (1,2), by McKernan and colleagues (3,4) and via a white paper review from the Cannabis Safety Institute (5), Bear-McGinnis (11) and clinical papers by by Kagen et al (9) dating back to 1983, and (10) Cescon et al

The pilot studies from Thompson and McKernan are particularly informative, because in both instances assumptions were not made as to the role of any pathogen. Instead relatively bias free Next Generation sequencing was deployed.

McKernan concluded from their pilot study that,
"the toxigenic *Penicillium* species: *P. paxilli, P. citrinum, P. commune, P. chrysogenum, P. corylophilum, Aspergillus* species: *A. terreus, A. niger, A. flavus, A. versicolor* and *Eurotium repens*. In addition, a pathogenic species *Cryptococcus liquefaciens* was

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detected. The fungal microbiomes of the different samples differed significantly in the number and diversity of species present".

Thompson et.al found, in their NGS pilot *the presence of,*
"E. coli, *Klebsiella pneumonia*, *Pseudomonas aeruginosa*, *P. fluorescens* and *P. putida*, *Acinetobacter baumannii*, and *Stenotrophomonas maltophilia*. Although limited in coverage, WMGS reads from the samples analyzed mapped to the fungal genomes targeted: Sample 138-011 read (n=534) mapping supports the presence of *Alternaria alternata* and *Cladosporium sphaerospermum*. reads from sample MJ150-008 (n=658) indicated the presence of *A. fumigatus*, *C. laurentii* and *M. circinelloides*, all well-known causes of invasive fungal infections in immunocompromised hosts. We found numerous Gram-negative bacilli and fungal pathogens contaminating medical marijuana". Which are also known to be dangerous to immunocompromised patients.

As the authors of both the Thompson and McKernan pilots have both argued, these preliminary findings from next generation sequencing (NGS), the 'gold standard' in molecular typing. Both pilot studies were obtained via analysis of less than 2-dozen cannabis isolates from a number of growers.

What the pilot data do suggest is that, even among the sampling that was done, there is substantial variation among the small numbers of samples studied in terms of the relative abundance of the several pathogens detected and even the identity of the pathogens seen in each sample.

Based upon those findings, we summarize 3 important general principles of cannabis contamination, as deduced from the recent wide-ranging NGS data published within the past 6 months (1-4) and from the conclusions drawn by The Cannabis Safety Institute in 2015 (5):

1). Especially for the fungal contaminants, a much larger range of contamination was detected than previously generalized (in 2015 by the Cannabis Safety Institute). The systematic incidence of *P. paxilli, P. citrinum,* as seen by McKernan (3.4) was especially worrisome, since it was previously un-suspected and could be highly toxic to immunocompromised users. Kagen(10) concluded as far back in 1983 through a peer reviewed clinical study in the Journal of Clinical Immunology that:

The possible role of marijuana (MJ) in inducing sensitization to Aspergillus organisms was studied in 28 MJ smokers by evaluating their clinical status and immune responses to microorganisms isolated ,from MJ. The spectrum of illnesses included one patient with systemic aspergillosis and seven patients with a history of bronchospasm after smoking of MJ. Twenty-one smokers were asymptomatic. **Fungi were identified in 13 of 14 MJ samples and included *Aspergillus fumigatus*, *A. flavus*, *A.***

***niger*, *Mucor*, *Penicillium*, and *thermophilic actinomycetes*.** Precipitins to Aspergillus antigens were found in 13 of 23 smokers and in one of 10 controls, while significant blastogenesis to Aspergillus was demonstrated in only three of23 MJ smokers. When samples were smoked into an Andersen air sampler, A. fumigatus passed easily through contaminated MJ cigarettes. **Thus the use of MJ assumes the risks of both ,fungal exposure and infection, as well as the possible induction of a variety of immunologic lung disorders.**

2). The substantial variation in the number and nature of pathogen contamination among individual isolates, as seen in both pilots, in cannabis samples obtained from a number of growers, suggests that the range of pathogenic bacteria and pathogenic fungal contamination may be much larger than previously suspected. As the geographic range of cannabis cultivation is extended to many states, it may be necessary to continually update the list of important cannabis contaminants.

3). As both Thompson (1.2) and McKernan (3.4) have suggested, and as had been suggested by The Cannabis Safety Institute before them (5) the measurement of "Total Yeast and Mold" and "Total Bacterial Load" may be viewed as relatively useless analytical tests: the reason being that in both the bacterial and fungal complement of cannabis, the incidence of a toxic bacterial or fungal sub-fraction, may be unrelated to the very large excess of non-toxic bacteria or fungi in any sample.

Testing Recommendations to New Mexico, based on the scientific literature and observations made above.

1). **Bacteria**. Testing should be performed to explicitly detect toxic bacteria, especially the **E. coli** and **Salmonella** strains. Given that P. botulinum has been implicated in the early NGS testing, it should also be considered for addition to the New Mexico bacterial test panel so that its true incidence may be understood. **Bacterial subtyping for Enterobacter** should be considered for retention. Total bacterial load should be abandoned as a test, given that it produces a meaninglessly high false positive rate.

2). **Fungi**. Testing should be performed to explicitly detect toxic yeast and mold, especially the toxic **Aspergilli (flavus, Niger, terreus, Fumigatus**) and **Penicillium (citrinum, paxilli)** which have been implicated as present in pilot studies. Total Yeast and Mold load should be abandoned as a test, given that it produces a meaninglessly high false positive rate in many instances.

3). **Nucleic Acid Tests Should be Deployed in a way that Bypasses Cell Culture**. The references Cited (1-5) all suggest that great care be taken in the interpretation of plate based culture methods, in that pathogen viability may be lost

during cannabis processing (especially drying) and during ambient temperature transit from the grower/processer to the testing lab (e.g. see ref 6).

Such Pre-analytical variables are likely to affect cell viability but not DNA yield, thus methods should be found to obtain a DNA-based estimate of bacterial and fungal contamination in ways that are not based on culture enrichment, given that culture based enrichment skew the pathogen profile.

4). **Nucleic Acid and Culture Based Methods Should both be Used Mindfully**: **Understanding meaning of Culture vs Culture independent methods Microbial Contamination**. The traditional argument for the superiority of plate-based microbial culture analysis or culture independent analysis after a preliminary fluid based or plate based culture enrichment is that both such culture based approaches reveal the identity of the "culturable" sub fraction of a microbial contaminated sample, where as a nucleic acid test, done without enrichment gives the "Total" microbial load: both "culturable" and "nonculturable".

Given the rapidly growing diversity of both the bacteria and fungi of interest in cannabis testing, the references cited (1-5) all argue that culture conditions must be fine-tuned and validated to accommodate the diverse growth needs of the different microbial antigens. The finding of culturable material is nearly always a solid finding. However, there is now substantial data to suggest that potentially viable microbial contamination may reside in a sample, but especially when many different pathogens must be detected at the same time, the diversity of multiple culture conditions needed may yield a distribution of "culturable" pathogens that is greatly skewed relative to the true distribution of "potentially culturable" pathogen in the sample, or in the extreme case (as often seen for fungi) the production of overt false negatives: i.e. potentially-culturable pathogens which simply did not amplify under the culture conditions chose.

5) It has been clearly demonstrated that enrichment culturing of microbes can introduce bias, both positive and negative, which can yield inaccurate representation of the original microbial population in the sample.

Scientific evidence has been presented in a number of peer-reviewed scientific articles which include: 1) Kerr, J.R. (1999) *Bacterial inhibition of fungal growth and pathogenicity*. Microbial Ecology in Health and Disease, 11:3, 129-142; and 2) Dunbar, J., White, S., and Forney, L. (1997) *Genetic Diversity through the Looking Glass: Effect of Enrichment Bias*. Applied and Environmental Microbiology, 63(4), 1326-1331.

Additional scientific evidence has been provided that shows how enrichment yields inaccurate results specifically as it relates to cannabis include McKernan, Spangler, et

al,(2016) Metagenomic analysis of medicinal Cannabis samples; pathogenic bacteria, toxigenic fungi, and beneficial microbes grow in culture-based yeast and mold tests.

6) In addition, common enrichment protocols permit aerobic and facultative anaerobic bacteria to grow but does not permit obligate anaerobes, such as Clostridium botulinum, to grow. This renders many laboratories from adequately testing for obligate anaerobes which can pose a very significant health hazard to consumers of products inhabited by them. Molecular methods can be used to negate the bias effect of enrichment culturing, as well as permit screening for presence of obligate anaerobes.

7) **Recommend adding Clostridium botulinum, producer of the life threatening botulinum toxin** (Peck, M. W., Stringer, S. C. & Carter, A. T. Clostridium botulinum in the post-genomic era. Food Microbiol. 28, 183–191 (2011)) as a required organism as it is a relatively common bacterium found in soil samples and it has been associated with outbreaks involving food oil products (Centers for Disease Control and Prevention (CDC). Type B botulism associated with roasted eggplant in oil--Italy, 1993. MMWR Morb. Mortal. Wkly. Rep. 44, 33–36 (1995), and Morse, D. L., Pickard, L. K., Guzewich, J. J., Devine, B. D. & Shayegani, M. Garlic-in-oil associated botulism: episode leads to product modification. Am J Public Health 80, 1372–1373, (1990)) due to the microenvironment of a hydrophobic and anaerobic conducive towards C. botulinum cell and spore growth, This is particularly analogous to the oils and other hydrophobic extracts using materials from Cannabis, and ingestion of C. botulinum cells/spores can find niches within the digestive tract to permit growth and production of the botulinum toxin.

In the context of those arguments, the cannabis testing industry needs to host a discussion to assign the proper use of both nucleic acid and culture based methods. In the area of food safety testing, Nucleic Acid testing is now considered the most conservative type of test, when a large panel of pathogens must be measured in parallel: especially when the nucleic acid testing can be done without a potentially-skewed pre-culture step which precedes the nucleic acid test: see for instance the USDA White paper ref 6)

If you have any questions please contact Dr. Michael Hogan, mhogan@pathogendx.com or Dr. Carl Yamashiro, cyamashiro@pathogendx.com, and Dr. Ben Katchman, bkatchman@pathogendx.com

Regards,

Milan Patel

PathogenDx
Setting the standard in DNA testing

CEO
PathogenDx

References Cited.

1). Thompson GR,, Tuscano JM. **Adverse health effects of marijuana use.** N Engl J Med 2014; 371(9):878-9.

2). Thompson GR, Tuscano JM, Dennis M, Singapuri A, Libertini S, Gaudino R, Torres A, Delisle JM, Gillece JD, Schupp JM, Engelthaler DM. **A microbiome assessment of medical marijuana**. Clin Microbial Infect. 2017 Apr;23(4):269-270. doi: 10.1016/j.cmi.2016.12.001. Epub 2016 Dec 9.

3). McKernan K, Spangler J, Helbert Y, Lynch RC, Devitt-Lee A, Zhang L, Orphe W, Warner J, Foss T, Hudalla CJ, Silva M, Smith DR. **Metagenomic analysis of medicinal Cannabis samples; pathogenic bacteria, toxigenic fungi, and beneficial microbes grow in culture-based yeast and mold tests.** F1000Res. 2016 Oct 7; 5:2471. eCollection 2016.

4). McKernan K, Spangler J, Zhang L, Tadigotla V, Helbert Y, Foss T, Smith D.

Cannabis microbiome sequencing reveals several mycotoxic fungi native to dispensary grade Cannabis flowers. Version 2. F1000Res. 2015 Dec 10 [revised 2016 May 10]; 4:1422. doi:10.12688/f1000research.7507.2. eCollection 2015.

5). Holmes M, Vyas JM, Steinbach W, McPartland J. **Microbiological Safety Testing of Cannabis,** Cannabis Safety Institute, May 2015

6). Office of the Chief Scientist Food Safety Science. **White Paper U.S. Department of Agriculture Research, Education and Economics** July 24, 201 https://www.usda.gov/sites/default/files/documents/food-safety-science-white-paper.pdf

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7). Wilson M, Lindow SE. **Viable but Nonculturable Cells in Plant-Associated Bacterial Populations.** Chapter in "Nonculturable Microorganisms in the Environment", Colwell RR, Grimes DJ, eds. Springer, 2000.

8). Hibbing ME, Fuqua C, Parsek MR, Brook Peterson S. **Bacterial competition: surviving and thriving in the microbial jungle.** Nat. Rev. Microbial. 2010 Jan; 8(1): 15-25. doi: 10.1038/nmicro2259.

(9) Kagen et al. **Marijuana Smoking and Fungal Sensitization**. J Allergy Clin Immunol. 1983.

(10) Cescon et al. **Invasive Pulmonary Aspergillosis Associated with Marijuana Use in a Man with Colorectal Cancer**. Journal of Clinical Oncology. 2008.

(11) Bear-McGuinness. **Thousands of Types of Fungi, Bacteria Found in Californian Cannabis**. Analytical Cannabis. 2018.

From: Gonzales, Martinik, DOH
To: Woodward, Chris, DOH; Jimenez, Billy, DOH
Cc: Sundberg, Andrea, DOH
Subject: FW: [EXT] Error in New version of rules
Date: Thursday, January 2, 2020 10:20:30 AM

See below from Kathleen O'Dea. Andrea, I think this should be considered as public comment?

Martinik (Marti) Gonzales
License and Compliance Program Manager
Medical Cannabis Program
5301 Central NE, Ste. 204
Albuquerque, NM 87108
ph:(505) 841-5540
www.nmhealth.org

Facebook | Instagram | Twitter | LinkedIn

Accredited since 2015

-----Original Message-----
From: Kathleen ODea <kkodea@scepterlabs.com>
Sent: Thursday, January 2, 2020 10:19 AM
To: Peralta, Matthew, DOH <Matthew.Peralta2@state.nm.us>; Gonzales, Martinik, DOH <Martinik.Gonzales@state.nm.us>; Kunkel, Kathy, DOH <Kathy.Kunkel@state nm.us>
Subject: [EXT] Error in New version of rules

Matthew,
There is glaring error in the new version of the proposed rules. Please see proposed table for testing solvents. Ethylbenzene is not the same as meta xylene. Meta xylene is a separate chemical. Meta xylene and para xylene cannot be separated so the footnote is incorrect. Otho xylene can be separated from meta and para but with great difficulty and there would be no reason to do so.
Your rules state that ethylbenzene is the same as meta xylene. This is incorrect. The footnote states that ortho and pera cannot be separated. This is incorrect. Also, since meta xylene has been improperly identified as ethylbenzene the action level is incorrect

Please correct this. It is embarrassing for New Mexico to memorialize into law such an obvious error In addition the proposed rules require a calibration curve that contains the highest action level for certain solvents(2000 ppm) This is not possible. CRM is available at a maximum of 1000 ppm.
Thank you.
Kathleen ODea

Sent from my iPhone

[EXT] MCP Public Comment 1/13/19

[redacted]

Mon 1/13/2020 10:48 AM

To:comment, MCP, DOH <MCP.Comment@state.nm.us>;

Hello Andrea,

My name is [redacted] and [redacted]. This is my first time writing a comment. [redacted] I am here to help the State and LNPPs focus program efforts on the patients.

TOP Priority OPEN up "micro business" licenses immediately in preparation to compensate for Rec use is implemented. Allow small family farms and entrepreneurs to enter the market to be able to sell to LNPPs for Medical/Rec use, allow Micros to sell directly to medical patients who have specific needs.

- Allow 3rd party business to test, process and package for patients to have their medication administered as specifically needed: e.g. Tinctures, FECO, Topicals, extractions as well and edible manufacturing carts ECT.....
- Include program funded grows for veterans and a system set up for low-cost meds for those in poverty on fixed income and no ability to afford adequate medication.

Consumption areas for qualified patients, Should NOT be Limited to LNPP sites that are operated by any business to participate by approval of an application to be anywhere and everywhere. Near military bases, reservations, and near borderlines. PATIENTS NEED THIS!

Example: Tattoo shops to offer a dab for pain control, Huka Lounges, Hotels, Bud and Breakfast, cafes or coffee shops and restaurants with an infused cuisine menu.

"Cannabis testing to include also mold, heavy metals and to have a Member of the DOH to cut the samples from the bottom, middle, and tops.

Thank you for your time and consideration,

Kindest regards,

[redacted]

Re: [EXT] MCP Public Comment 1/13/19

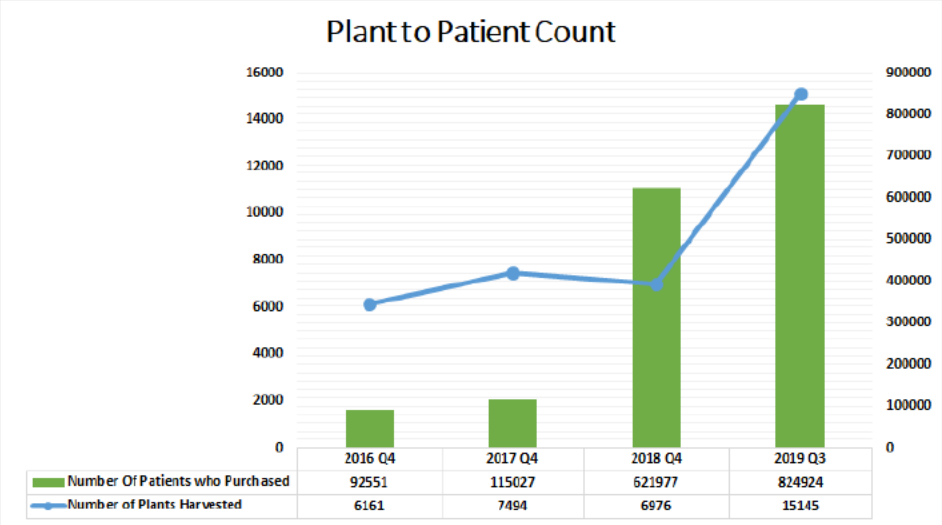
[redacted]

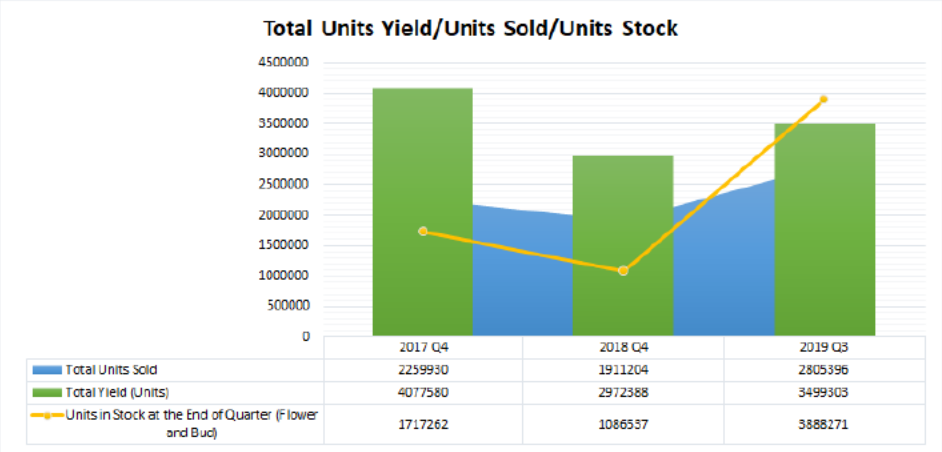
Tue 1/14/2020 1:18 PM

To:comment, MCP, DOH <MCP.Comment@state.nm.us>;

Thank you, Andrea!

I did just create some supporting graphs to show how Mico Business will help bridge the gap for patients, provide relief and give the LNPPs a chance to catch up on quantity for when recreational hits. Give our small town, mom and pop business a chance to thrive and do what New Mexicans do best, GROW!





My data source is NMDOH website: https://nmhealth.org/about/mcp/svcs/pdb/

I see that if we don't open up the micro-business a lot of Medical Cannabis Patients will go without, suffer and hope may be lost. Please help support New Mexicans. The New Mexico Medical Cannabis Patient Adovacate Alliance Officers are ready to help in any way.

[redacted]

On Mon, Jan 13, 2020 at 4:05 PM comment, MCP, DOH <MCP.Comment@state.nm.us> wrote:

Dear Ms.

Thank you fro your comment regarding the proposed regulation changes. Your comment will be reviewed and included as part of the public record.

Thank you,

Andrea Sundberg
State of New Mexico Department of Health
Medical Cannabis Program
Health Program Manager

From: [redacted]
Sent: Monday, January 13, 2020 10:48 AM
To: comment, MCP, DOH
Subject: [EXT] MCP Public Comment 1/13/19

Hello Andrea,

My name is [redacted] and I am an [redacted]. This is my first time writing a comment [redacted] and quickly started advocating. I am here to help the State and LNPPs focus program efforts on the patients.

TOP Priority OPEN up "micro business" licenses immediately in preparation to compensate for Rec use is implemented. Allow small family farms and entrepreneurs to enter the market to be able to sell to LNPPs for Medical/Rec use, allow Micros to sell directly to medical patients who have specific needs.

- Allow 3rd party business to test, process and package for patients to have their medication administered as specifically needed: e.g. Tinctures, FECO, Topicals, extractions as well and edible manufacturing carts ECT.....
- Include program funded grows for veterans and a system set up for low-cost meds for those in poverty on fixed income and no ability to afford adequate medication.

Consumption areas for qualified patients, Should NOT be Limited to LNPP sites that are operated by any business to participate by approval of an application to be anywhere and everywhere. Near military bases, reservations, and near borderlines. PATIENTS NEED THIS!

Example: Tattoo shops to offer a dab for pain control, Huka Lounges, Hotels, Bud and Breakfast, cafes or coffee shops and restaurants with an infused cuisine menu.

"Cannabis testing to include also mold, heavy metals and to have a Member of the DOH to cut the samples from the bottom, middle, and tops.

Thank you for your time and consideration,

Kindest regards,
[redacted]

--
[redacted]

[EXT] Medical Cannabis Program rules public comment

[redacted]

Tue 1/14/2020 9:44 PM

To: comment, MCP, DOH <MCP.Comment@state.nm.us>;

Hello. I write to you on behalf of myself and the New Mexico cannabis patients. I am asking you to open up licensing! Quality of medicine (cannabis) is at a all time low. Prices are higher than ever. Dispensaries feed resources into expanding and preparing for recreational rather than providing quality medicine for a decent price. Higher plant counts haven't improved prices. Allowing discounts on larger purchased amounts did not lower prices. For the sake of the medical cannabis patients please allow more licenses to be issued. People are suffering in rural areas most due to the high prices, high demand and low quality. Allowing more producers will help fill demand and help keep medical cannabis patients from going back to the black market for their cannabis due to low quality and high price at dispensary.

Ultra Health®

Andrea Sundberg
NM Department of Health
Medical Cannabis Program
P.O. Box 26110
Santa Fe, NM 87502-6110
MCP.comment@state.nm.us

Re: Comments on Proposed Rules NMAC 7.34.4; Public Hearing January 16, 2020

Dear Department of Health,

The purpose of this letter is to provide New Mexico Top Organics-Ultra Health's ("Ultra Health's) comments upon proposed amendments to various rule sections of the Department's Medical Cannabis Program rules at Parts 7.34.4 NMAC, which are to be considered at a public hearing scheduled for January 16, 2020.

GENERAL CONCERNS ON TIMING:

It is unclear why the NMDOH is moving to promulgate such extensive and suppressive regulations in light of the upcoming 30-day legislative session and Governor Michelle Lujan Grisham's instruction of putting legalization of cannabis for adult use on her call.

The short 30-day session begins Tuesday, January 21, 2020 and ends February 20, 2020. The bill addressing the legalization of cannabis for adult use has been drafted and submitted already. The draft bill has been shared with those impacted state agencies and including the NMDOH. In the bill as drafted and distributed, NMDOH would lose all regulatory powers for the Medical Cannabis Program and strictly be limited to only the maintenance of the patient registry. The Regulation and Licensing Department will be given the power to regulate and promulgate new rules for both medical and adult-use cannabis activities.

The NMDOH, other state agencies and current stakeholders dealing with prospects of these new proposed rules will be in a far better position to comment after the conclusion of this short 30-day session. In fact, the outcome of this legislative cycle will be known in approximately 35 days.

It is illogical to move to promulgate new rules for the Medical Cannabis Program when these rules will ultimately become obsolete or require even greater programmatic integration with the adult use program. Immediately, RLD will need to begin a new regulating process for the existing medical program, all of which will occur on the effective date of the legalization bill,

estimated to be July 1, 2020. RLD will be specifically mandated to create its own regulations, which NMDOH is surely aware of.

It is questionable at best for NMDOH to promulgate new rules that are far more limiting and resource-intensive considering the rules NMDOH has refused to promulgate – rules that support an adequate supply for patients. Rather than promulgate obsolete rules, NMDOH efforts should be focused on lifting the scant, unsupported purchase limits and allowing current cannabis producers to cultivate enough plants to serve patient needs. In addition, there should be an added emphasis on preserving and reaffirming the ability for vertically integrated licensing considering the upcoming legalization of cannabis for adult use.

NMAC 7.34.4.7; Definitions

Although the Department of Health ("DOH") has made some effort in its proposals to make reference to statutory authority, there are several definitions in NMAC 7.34.4.7 that still, inexplicably, do not match or track statutory definitions. The Lynn and Erin Compassionate Use Act, NMSA 1978 § 26-2B-3, contains 28 different definitions. The inclusion of so many definitions within the statute indicates the Legislature wished to take care to define and direct the Medical Cannabis Program. Despite the Legislature's care, DOH has continued to change the explicit direction of the Legislature.

The regulatory definitions of "cannabis courier," "cannabis manufacturer," "cannabis producer," "manufacture," and other terms do not match the definitions set out in statute. For example, "cannabis courier" in statute is a person "licensed" by DOH, whereas in regulation it is a person "approved" by the department. Likewise, "cannabis manufacturer" in statute is an entity "licensed" by DOH, whereas "manufacturer" in regulation is a person "approved." A "cannabis producer" in statute is "a person that is licensed by the department to possess, produce, dispense, distribute and manufacture cannabis and cannabis products and sell wholesale or by direct sale to qualified patients and primary caregivers," but a "licensed producer" in regulation is "a person or entity licensed to produce medical cannabis." "Manufacture" in statute means "to prepare a cannabis product," but "manufacture" in regulation means "to make or otherwise produce cannabis-derived product or concentrate."

The statute contains definitions for "cannabis establishment," "cannabis product," "cannabis testing facility," "hemp," "license," "licensee," "produce," and others, but the regulations do not contain these definitions.

As DOH knows, the issue of DOH's regulatory authority has arisen several times in litigation regarding the proper implementation of the Compassionate Use Act. When DOH uses different definitions than the statute does, the difference spreads confusion among medical cannabis businesses and patients. The differences also breed an atmosphere of distrust between medical cannabis business and DOH, because the businesses cannot serve two masters—both the statute and the regulation.

It is both legally proper and beneficial to the business-DOH relationship to ensure that regulations match statutory language. It is beneficial to the business-DOH relationship because it creates consistent standards and eliminates confusion. It is legally proper because "When an agency construes a statute that governs it, the court will accord some deference to the agency's interpretation," but "we are less likely to defer to an agency's interpretation of the relevant statute if the statute is clear and unambiguous, as it is in this case," and "if statutory construction is not within the agency's expertise, this Court should afford little, if any, deference to the agency on issues of statutory construction." *Marbob Energy Corp. v. New Mexico Oil Conservation Commission*, 2009-NMSC-013, ¶ 6-7, 206 P.3d 135. Additionally, between a statute and a regulation, the statute trumps the regulation. "When a statute and a regulation conflict, the statute prevails." *Gallegos v. State Bd. of Education*, 1997-NMCA-040, ¶ 23, 123 N.M. 362.

Certainly, DOH may add more definitions to its regulations than appear in statute. However, DOH's attempts to change the explicit wording of the statute is improper and inexplicable. The regulatory definitions should exactly match any definition given by statute.

NMAC 7.34.4.8(Z); Geographical Regions

This part of the proposed regulations states, "The department may additionally restrict the licensing of non-profit producers to applicants that commit to production and distribution of usable cannabis in specific geographical locations of the state."

Commenter Ultra Health believes strongly in serving rural areas of New Mexico, and for that reason, Ultra Health has opened dispensaries in 13 of out 33 counties in New Mexico.

Although DOH certainly expresses the right sentiment with this proposed regulation, its effect is unfortunately ambiguous. It is not clear whether this "restriction" applies to *new applicants* for a license or *applicants for re-licensure*. That is, will DOH consider the commitment to underserved areas only for applicants seeking entirely new licenses, or will DOH consider the commitment when it re-licenses entities who have held licenses for years? If DOH applies this criterion to already-licensed entities who are going through re-licensure processes, this criterion could result in closure of smaller producers and could disrupt production and patient access.

Additionally, the placement of this proposed regulation is odd. NMAC 7.34.4.8(F) already sets out "factors considered" in "determining the number of licenses" and which entities shall be licensed. If DOH is concerned about applicants' commitments to underserved areas, then it could add that as a "factor considered" in granting license applications in the first place.

NMAC 7.34.4.9; Minimum Standards for Production

Commenter Ultra Health believes the sentiment expressed by NMAC 7.34.4.9 is correct, but the vagueness of some of the provisions here will result in unworkable standards. Ultra Health believes that the general level of professionalism in New Mexico's medical cannabis industry should be increased, and Ultra Health believes that cannabis businesses should strive for high levels of quality control and technical accomplishment.

However, the level of strictness of 7.34.4.9 is positively draconian and may very well drive smaller producers out of business due to the costs of compliance. For example, 7.34.4.9(A)(1) requires compliance with "zoning, occupancy, licensing, and building codes." Many producers in New Mexico rent their premises and have little control over building codes. Placing the burden on producers means producers will have to spend significant sums on building code reviews and renovations in rented premises.

There are also vagaries that produce absurd results. For example, the requirement that all "equipment, implements, and fixtures shall be used exclusively for the production of cannabis" means that a microwave in an employee break room would be disallowed, and that the computer used to run BioTrack is disallowed. One provision here requires production to be conducted "in a manner that does not allow cross-contamination from chemical or biological hazards," without a precise definition of "hazards." Such innocuous substances as water or oxygen can quickly become hazards under specific conditions.

NMAC 7.34.4.9(A)(12)

One particularly problematic provision is NMAC 7.34.4.9(A)(12), requiring that "floors, walls, and ceilings are constructed in such a manner that they are washable, wipeable, and non-absorbent, and can be kept clean, and kept in good repair." This requirement is simply unworkable for the medical cannabis industry. It seems to have come from a food manufacturing setting, but DOH forgets that a medical cannabis facility combines an agricultural operation with a manufacturing operation.

Some producers still grow outdoors, in soil, and soil can never be made non-absorbent. Outdoor growers are also quite incapable of having "washable" ceilings, in that their ceiling is simply open sky.

Ultra Health itself grows in greenhouses with floors made of gravel; the purpose of the gravel is to allow excess water to flow away. The alternative—a non-absorbent floor—would mean that the plants are watered, and the excess water simply stands in pools on concrete. Standing water is a much more dangerous breeding ground for contaminants than gravel is.

If Ultra Health is made to renovate its greenhouses with non-absorbent flooring, it will have to pour concrete on the floor of the greenhouses; this will put the greenhouses out of operation for quite some time. It will also require Ultra Health to change its growing systems to install some method for drainage, so that water will not pool on the concrete floor. This will be another investment and will also take the greenhouses out of operation for a significant period.

Ultra Health understands DOH's purpose with this requirement: to ensure cleanliness. However, DOH must remember that cannabis is, first and foremost, an agricultural product grown in agricultural conditions. The manufacturing side is more akin to the food production field, from which DOH obviously took these regulations.

DOH must separate the growing from the processing and finishing. The growing stages should be subject to agricultural standards, while the processing and finishing should be subject to manufacturing standards. DOH has combined the strictest part of both worlds, and in doing so, has jeopardized the very existence of many producers.

NMAC 7.34.4.9(A)(3)

This provision requires a producer to ensure "that no cannabis plants other than those grown pursuant to the non-profit producer's production license from the department are grown on the premises of the non-profit producer, including but not limited to hemp plants."

This provision effectively prohibits a producer from co-housing medical cannabis plants and industrial hemp plants on the same campus. Now, the first problem here is one of vagueness: what is a "premises?" Are premises defined by the address of a property? By who owns which parcel of an addressed property? By fences? By walls?

The larger problem is that DOH exceeds its statutory authority by claiming power to regulate the location of hemp. When the Legislature legalized the cultivation of industrial hemp, it gave regulatory authority over hemp to the Department of Agriculture. See NMSA 1978 § 76-24-2 (2017). The Department of Health, on the other hand, has never been given any kind of regulatory authority over hemp.

DOH is now attempting to regulate the locations where hemp may be grown, and in doing so, DOH is usurping the regulatory authority of the Department of Agriculture. DOH can exercise limited control over where medical cannabis may be grown, but it cannot exercise control over where hemp is grown.

Furthermore, the limited ability of DOH to control where medical cannabis is grown does not include placing restrictions on what other crops may be grown alongside medical cannabis. NMSA 1978 § 26-2B-7(A)(6) provides that "production facilities" must be "housed on secured grounds and operated by licensees" and that other facilities must be "not within three hundred feet of any school, church or daycare center."

Now, as DOH will recall, Ultra Health obtained a writ of mandamus from the Thirteenth Judicial District Court in case D-1329-CV-2018-01854. That writ held that DOH could not place location restrictions on dispensaries other than the 300-feet rule. In a larger sense, the writ stands for the proposition that DOH cannot restrict land use of producers in a manner not set out in statute.

Here, statute sets out that production facilities must be secure, but it does not otherwise restrict how producers use their property. The statute does not specify indoor or outdoor grows, does not require labeling of the property to passers-by, and does not prohibit colocation of other activities.

Ultra Health believes that DOH, by prohibiting colocation of hemp and medical cannabis, is going beyond the bounds of statute. Now, Ultra Health would not oppose a regulation that

required reasonable segregation of hemp and medical cannabis within a premises or campus, such as with walls, fences, and signage. This type of segregation would be done only to ensure that the respective regulators of DOH and DOA could tell the plants apart.

NMAC 7.34.4.10; Testing

Once again, Ultra Health applauds the sentiment of NMAC 7.34.4.10—to increase the quality of medical cannabis produced in New Mexico—but must express serious reservations with the rule based upon potentially devastating effects.

Impossibility of Testing

The rule requires much more testing than is currently required. Currently, there are one-and-a-half laboratories in New Mexico that handle medical cannabis. Ultra Health says "half" of a laboratory because Scepter Lab laboratory is located in Santa Fe. The other laboratory, Rio Grande Analytics, is located in Las Cruces. It has been Ultra Health's experience that when couriers travel with medical cannabis to Las Cruces, federal Immigration and Customs Enforcement agents at the checkpoint in Las Cruces often take the cannabis and never return it.

If Scepter Lab shuts down entirely or shuts down partially, producers will have to rely on the laboratory in Las Cruces, and that will result in a high likelihood of federal agents taking the cannabis, thus preventing a test and disrupting the entire supply chain. Relying on the Las Cruces laboratory works well for producers who grow their plants south of the checkpoint at Las Cruces, but producers growing in central or northern New Mexico cannot rely on sending samples to Las Cruces knowing that they may be taken by federal agents.

Furthermore, DOH's new proposed regulations set much more stringent standards for many items than are currently in place. Ultra Health and the other producers do not even know if the laboratories are capable of testing to this level of specificity. Testing to these standards may require new and expensive equipment, with the result that no producer can pass the tests because no laboratory can do the test.

Additionally, it is not apparent that the existing laboratories can handle the volume of testing that will be required once plant counts increase. As DOH knows, the plant limitation has recently been raised from 450 to 1,750. Now, at 450 plants, Ultra Health was doing 400 batch sample tests per month. Ultra Health estimates it will be doing 2,000-3,000 tests per month at 1,750 plants.

Now, NMAC 7.34.4.10(A) does provide that DOH may waive testing if laboratories are not able to perform the tests. However, mere ability should not be the only factor in waiving testing requirements. A laboratory may have the *ability*, but the test may 1) take so long; or 2) cost so much, that the result is delayed product or product too expensive for patients. DOH, in focusing on laboratories' ability, ignores a holistic view of the market. What good is a product subject to the most rigorous tests if it ends up being too expensive for patients and takes too long to obtain? DOH states its purpose in implementing these rules is to ensure "beneficial use," as is

the purpose of the Compassionate Use Act. A product that is too expensive or takes too long to get is not "beneficial."

DOH Does Not Know if Producers Will Be Able to Meet the Standards

Another glaring problem with NMAC 7.34.4.10 is that DOH has no idea if most producers will be able to meet the requirements at a reasonable rate. DOH of course must have testing requirements, but it must balance stringency of testing requirements with overall health of the market. If 95% of products fail the most stringent of testing requirements, is that acceptable to DOH and to patients? If 10% of products fail, is that acceptable?

DOH should adopt a pilot program to test the test—to find out if these are workable standards. Indeed, the standards proposed by DOH are as strict or stricter than those of many other states, including states that have had robust and well-supported programs for much longer than New Mexico has. See, for example, the testing requirements of California and Colorado, attached here.

Incidentally, stricter testing standards in Colorado and California have had negative effects on those states' legal programs, as higher testing expenses are passed on to the consumer and consumers go to the black market instead of staying within the legal market. DOH should look to the negative experiences of these states and ask if lowering a standard by a few parts per million is worth sick patients going to the illegal market to obtain cannabis.

A pilot program, under which the stricter testing is done but the current testing is enforced, would be useful in demonstrating to DOH if the stricter testing mode is necessary or achievable. The pilot program could also provide an indicator on how testing influences black market infiltration—will consumers pay the extra price and wait longer for legal products, or will they return to the black market?

DOH Has Failed to Consult the Medical Advisory Board

Now, Ultra Health itself does have a very rigorous quality control program that influences production practices from seed to sale, and Ultra Health believes very strongly in placing patients' safety above all else. However, it does not seem that DOH has actually consulted the Medical Advisory Board about the proposed testing standards in order to determine if they truly improve patient health.

The Medical Advisory Board is created by statute, NMSA 1978 § 26-2B-6 (2019). The statute creating the Medical Advisory Board does not explicitly say DOH must consult it regarding testing requirements, but given the Board's existence, it would seem strange *not to consult* it on these testing standards. The Board exists to provide professional advice to DOH on the management of the Medical Cannabis Program, and testing standards is right up the Board's proverbial alley.

Indeed, it seems arbitrary, capricious, and absurd for DOH to promulgate rules on safety standards for medical cannabis without consulting the Medical Advisory Board. The Board

should have been consulted to determine 1) if the current supply of medical cannabis from licensed entities is not safe enough; 2) if legal sources of medical cannabis were sickening patients at unacceptable rates; 3) if more stringent testing standards would improve safety; 4) if the testing standards were properly balanced against other negative effects, such as increased price and decreased supply.

The failure of DOH to obtain the advice of the Medical Advisory Board regarding testing standards indicates DOH's promulgated standards are arbitrary, capricious, and simply plucked from the air, rather than being the product of scientific consensus.

More Stringent Standards Will Decrease Supply

It also appears DOH has failed to consider how more stringent testing will impact supply. First, there is the impact of the sampling size. The new rules require batch testing and require "off-the-shelf" testing (see 7.34.4.10(C)(6), "Random testing of finished cannabis derived products). Ultra Health calculates that all testing combined will consume one half-pound of every five-pound batch. And of course, the testing called for by DOH is, by its nature, destructive testing—the test destroys the cannabis.

This means 10% of harvested cannabis will be consumed by testing alone. In turn, this means 10% of supply goes to testing rather to patients. If DOH truly wishes to require that much testing, it must adjust the plant count to make up for the material lost to testing.

Additionally, more stringent standards will lead to higher failure rates, and higher failure rates will mean more cannabis is destroyed than goes to patients. Cannabis that does not pass tests and cannot be remediated will be destroyed. The more cannabis destroyed is more cannabis that cannot serve patients.

In this way, more stringent standards drive down supply. If DOH wishes to tighten testing standards, it must know that this will negatively affect supply. The loss to testing failure must be made up with an increase to the plant count.

When DOH calculated patient demand in the spring of 2019, it did so without calculating the amounts lost to failed tests. That is, it calculated the amount of cannabis "sufficient" to meet patient needs in an imaginary, perfect world where no cannabis ever failed tests. However, this is not a perfect world, and if 25% of cannabis fails tests and is un-saleable, the plant count limitation must be adjusted up by 25% to account for that loss.

This shows, yet again, that managing a medical cannabis market requires balancing different factors. It is highly unlikely that DOH can achieve a working market with both high testing standards and low plant limitations. It would be more likely to achieve a working market with high testing standards and high plant limitations, or lower standards and lower limitations.

To use a popular colloquialism, DOH wants to have its cake and eat it too: it wants to keep plant counts too low to account for plant material lost to failures of stringent testing

standards. These testing standards will only result in decreased supply, higher prices, and more patients being driven to the black market.

The Standards Will Result in Producers Closing Their Businesses or Selling Licenses

Ultra Health predicts that instituting uniformly stringent testing standards, without a period for adjustment and without an indication that patient safety is currently compromised, will result in smaller producers closing their businesses or selling licenses to out-of-state interests.

Some producers will simply not have the wherewithal to achieve more stringent standards. The cost of improving their techniques will be very high, and lack of access to capital will prevent them from instituting capital improvements. This will then result in a markedly reduced output or closure of the business entirely. Additionally, current licensees will look to out-of-state interests to buy licenses. This would set a bidding war that does not serve the interests of New Mexico patients.

Currently, both large and small licensed producers face a litany of challenges to the survival of their businesses: 1) the punitively high licensing fees demanded by DOH; 2) punitive tax treatment that results in very large tax burdens; 3) lack of access to capital because of restrictive federal laws; 4) constant competition from the black market; 5) high costs of production because of high energy and water costs. On top of this, DOH adds stringent testing standards that could result in failure rates as high as 95%. In this antagonistic atmosphere, producers could simply start closing.

NMAC 7.34.4.10(E)(5)

NMAC 7.34.4.10(E)(5) provides, "repeated failure to pass testing may result in the imposition of disciplinary action(s) by the department, consistent with this rule."

DOH does not give any indication of what it considers to be "repeated." As stated above, Ultra Health plans to conduct 2,000 to 3,000 tests per month. Of course, there will be repeated failures given this high number of tests. This begs the question of whether two failures will subject a producer to disciplinary action, and certainly, every single producer will have more than two failures.

The producers and manufacturers need to know what DOH considers to be an unacceptable number or percentage of testing failures. When coming to those numbers, DOH should consider that the medical cannabis industry is different in important ways from pharmaceutical manufacturing or food manufacturing. Pharmaceutical manufacturing deals with often inert chemicals, but cannabis producers must deal with a living plant that has all the complexities of a living being.

The variability and failure rate of, say, bread will naturally be different from the failure rate of, say, Coca-Cola, given that bread is made with living microbes (yeast) and Coca-Cola is made from inert sugar. Likewise, the variability and failure rate of cannabis products will be

higher than other medicinal products because of the simple fact that cannabis plants are living beings that respond to their environments.

Ultra Health asks that DOH consult with the Medical Advisory Board to come forth with proposals for unacceptable rates of testing failures, with special attention paid to the context of medical cannabis cultivation.

Conclusion on Testing

The institution of more rigorous and stringent testing standards and protocols obviously derives from good intentions, but the new rules will result in more negative than positive consequences to the Medical Cannabis Program as a whole.

NMAC 7.34.4.14; Manufacturing Provisions

NMAC 7.34.4.14(B)(3) requires submission of a "hazard analysis critical control point plan" for each type of product manufactured. Again, it appears DOH has derived this requirement from food manufacturing regulations. HACCPs are in fact heavily regulated by the federal FDA, such that the FDA has an extensive article on HACCP guidelines on its website: https://www.fda.gov/food/hazard-analysis-critical-control-point-haccp/haccp-principles-application-guidelines

A recent study by the food industry found that developing a HACCP costs around $25,000 per product for "small establishments." See https://foodindustryexecutive.com/2017/02/how-much-food-safety-compliance-really-costs-for-meat-and-poultry-report/, also attached here.

Now, even if a manufacturer can afford to develop a HACCP plan, it is not apparent what expertise DOH has to judge it. That is, does DOH have employees with expertise in HACCP plans to know if a manufacturer has submitted a genuine one or simply a garbled collection of nonsense.

This is the difficulty in DOH attempting to regulate a subject matter more traditionally regulated by, say, the Department of Environment, or Regulation & Licensing. If DOH is to demand a HACCP, manufacturers must be assured that those plans will be evaluated by regulators with expertise in the area, and not by inexperienced DOH officials with no real training in food safety.

Again, DOH must balance the 1) perceived need for HACCPs; 2) the actual need for HACCPs; and 3) the burden on manufacturers. Some manufacturers will simply forgo HACCPs and stop manufacturing a particular product. Others may invest in HACCPs but will pass the cost onto patients, resulting in higher prices and flight to the black market.

The recent "vaping crisis" has resulted in increased focus on the safety of tobacco and cannabis products. However, the nexus between HACCPs and the vaping crisis is not apparent.

After all, the culprit in serious "vaping" illnesses has been found to be Vitamin E acetate, and DOH's proposed regulations altogether ban the use of Vitamin E acetate.

This shows that DOH can create targeted regulations that reach specific dangers without having to place vague and expensive regulatory burdens on businesses. The specific prohibition on Vitamin E acetate is a reasonable, targeted mechanism designed to specifically reduce one very specific harm at almost no cost to manufacturers. On the other hand, demanding HACCPs is a very onerous burden whose broad reach is not designed to target a specific problem.

Furthermore, the recent "vaping crisis" has proven once again the danger of illicit and illegal sources of cannabis. DOH can most immediately protect the health of New Mexicans by encouraging use of legal sources of cannabis and discouraging illegal sources. Forcing legal manufacturers to raise prices will only discourage legal access and encourage illegal sales.

Again, Ultra Health must ask if the Medical Advisory Board recommended HACCPs or sees a need for them. Ultra Health does not know if DOH has been inundated by patient complaints recently, but if DOH has, it should inform producers and manufacturers so that businesses can make targeted improvements. A HACCP requirement, without evidence of a broad spectrum of patient complaints, is like using a bulldozer to kill a mosquito. Rather, DOH and manufacturers should work together to find specific solutions to specific problems.

NMAC 7.34.4.14(C) Conflates "Additive" and "Addictive"

NMAC 7.34.4.14(C) is titled "prohibited additives" and then states manufacturers shall not "combine nicotine, caffeine, or any other addictive substance" with cannabis. This seems to conflate "additive" with "addictive."

The word "addictive" is not useful if it is not defined. First and foremost, sugar is now considered an addictive substance by many medical professionals. Read broadly, this rule would prohibit the combination of sugar with cannabis, and would therefore ban such products as cannabis gummies, cannabis hard candies, cannabis cookies, cannabis brownies, cannabis lollipops, etc. Prohibiting the use of sugar would decimate the market for edible products.

Ultra Health agrees that certain substances should not be combined with cannabis, but it asks for a specific list given that "addictive" could very well apply to sugar.

NMAC 7.34.4.27; Reciprocity

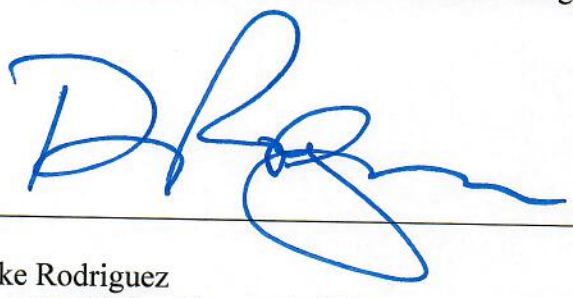
Ultra Health notes several ambiguities in the provisions regarding reciprocal participation and requests DOH clarify these points so that the reciprocal program may be implemented smoothly.

The rule requires participants to "register with a licensed non-profit producer." Ultra Health assumes this means out-of-state visitors can register with multiple producers and is not restricted to one.

Ultra Health also assumes that this "registration" will be visible to all producers, because all producers must be able to see a person's purchase history in order to ensure that the person does not purchase greater than 230 units within a 90-day period.

CONCLUSION

Ultra Health requests the Department review these comments in the context of improving the overall health of the Medical Cannabis Program to ensure its long-term success.



Duke Rodriguez
Ultra Health President and CEO

SUBMITTED: January 15, 2020

From:	Jason Barker
To:	Sundberg, Andrea, DOH; Zurlo, Dominick, DOH
Subject:	[EXT] Typo in Proposed Rules , page 19 ?
Date:	Wednesday, January 15, 2020 4:14:50 PM
Attachments:	Screenshot 2020-01-14 at 05.32.19.png Screenshot 2020-01-14 at 05.32.49.png

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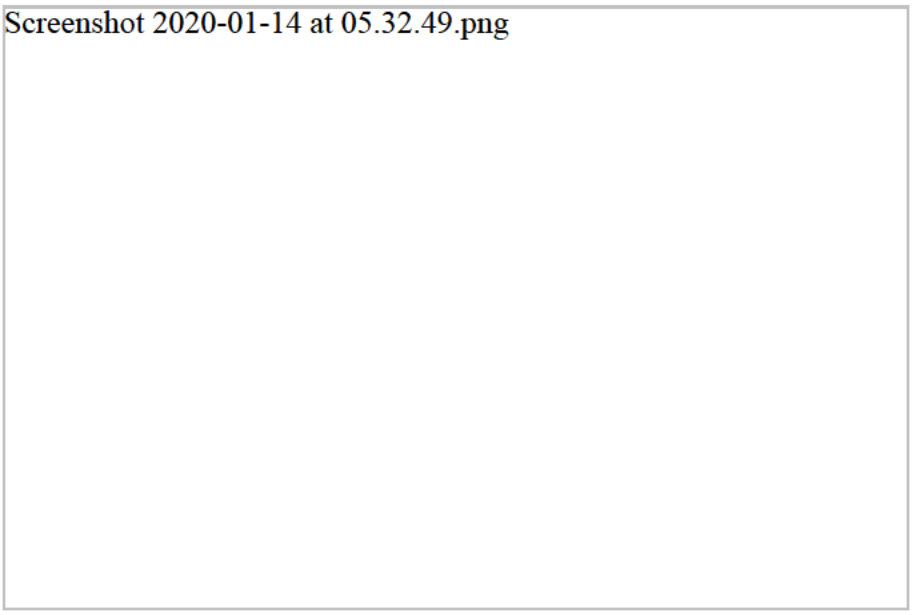
Hello,
I tried a few time today calling for both of you and got no where with Odessa who answered the phone.
In the proposed rules in the pictures below two of the lab test call for a 10 gram batch sample and I think this is a typo and should be 1.0 gram. I think that because all state labs in other state use 1.o gram for those same tests (Absence of Salmonella & E. coli; Total Aerobic Microbial Count; Total Combined Yeast & Mold Count; Bile-tolerant Gramnegative Bacteria; Total Coliforms Count)
That 10.0 grams for a batch sample twice on page 19 must be a typo?
https://nmhealth.org/publication/view/rules/5404/

Screenshot 2020-01-14 at 05.32.19.png



Thanks ,
Jason

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[redacted]

www.cannabisnewsjournal.co
[redacted]

Americans For Safe Access - Member
American Cannabis Nurses Association - Member
[redacted]

"The American Medical Association has no objection to any reasonable regulation of the medicinal use of cannabis and its preparations and derivatives. It does pretest, however, against being called upon to pay a special tax, to use special order forms in order to procure the drug, to keep special records concerning its professional use and to make special returns to the Treasury Department officials, as a condition precedent to the use of cannabis in the practice of medicine."
~Wm. C. Woodward, Legislative Counsel - 11:37 AM Monday, July 12, 1937

[EXT] Medical Cannabis Program rules public comment

[redacted]

Tue 1/14/2020 9:44 PM

To: comment, MCP, DOH <MCP.Comment@state.nm.us>;

Hello. I write to you on behalf of myself and the New Mexico cannabis patients. I am asking you to open up licensing! Quality of medicine (cannabis) is at a all time low. Prices are higher than ever. Dispensaries feed resources into expanding and preparing for recreational rather than providing quality medicine for a decent price. Higher plant counts haven't improved prices. Allowing discounts on larger purchased amounts did not lower prices. For the sake of the medical cannabis patients please allow more licenses to be issued. People are suffering in rural areas most due to the high prices, high demand and low quality. Allowing more producers will help fill demand and help keep medical cannabis patients from going back to the black market for their cannabis due to low quality and high price at dispensary.

Ultra Health®

Andrea Sundberg
NM Department of Health
Medical Cannabis Program
P.O. Box 26110
Santa Fe, NM 87502-6110
MCP.comment@state.nm.us

Re: Comments on Proposed Rules NMAC 7.34.4; Public Hearing January 16, 2020

Dear Department of Health,

The purpose of this letter is to provide New Mexico Top Organics-Ultra Health's ("Ultra Health's) comments upon proposed amendments to various rule sections of the Department's Medical Cannabis Program rules at Parts 7.34.4 NMAC, which are to be considered at a public hearing scheduled for January 16, 2020.

GENERAL CONCERNS ON TIMING:

It is unclear why the NMDOH is moving to promulgate such extensive and suppressive regulations in light of the upcoming 30-day legislative session and Governor Michelle Lujan Grisham's instruction of putting legalization of cannabis for adult use on her call.

The short 30-day session begins Tuesday, January 21, 2020 and ends February 20, 2020. The bill addressing the legalization of cannabis for adult use has been drafted and submitted already. The draft bill has been shared with those impacted state agencies and including the NMDOH. In the bill as drafted and distributed, NMDOH would lose all regulatory powers for the Medical Cannabis Program and strictly be limited to only the maintenance of the patient registry. The Regulation and Licensing Department will be given the power to regulate and promulgate new rules for both medical and adult-use cannabis activities.

The NMDOH, other state agencies and current stakeholders dealing with prospects of these new proposed rules will be in a far better position to comment after the conclusion of this short 30-day session. In fact, the outcome of this legislative cycle will be known in approximately 35 days.

It is illogical to move to promulgate new rules for the Medical Cannabis Program when these rules will ultimately become obsolete or require even greater programmatic integration with the adult use program. Immediately, RLD will need to begin a new regulating process for the existing medical program, all of which will occur on the effective date of the legalization bill,

estimated to be July 1, 2020. RLD will be specifically mandated to create its own regulations, which NMDOH is surely aware of.

It is questionable at best for NMDOH to promulgate new rules that are far more limiting and resource-intensive considering the rules NMDOH has refused to promulgate – rules that support an adequate supply for patients. Rather than promulgate obsolete rules, NMDOH efforts should be focused on lifting the scant, unsupported purchase limits and allowing current cannabis producers to cultivate enough plants to serve patient needs. In addition, there should be an added emphasis on preserving and reaffirming the ability for vertically integrated licensing considering the upcoming legalization of cannabis for adult use.

NMAC 7.34.4.7; Definitions

Although the Department of Health ("DOH") has made some effort in its proposals to make reference to statutory authority, there are several definitions in NMAC 7.34.4.7 that still, inexplicably, do not match or track statutory definitions. The Lynn and Erin Compassionate Use Act, NMSA 1978 § 26-2B-3, contains 28 different definitions. The inclusion of so many definitions within the statute indicates the Legislature wished to take care to define and direct the Medical Cannabis Program. Despite the Legislature's care, DOH has continued to change the explicit direction of the Legislature.

The regulatory definitions of "cannabis courier," "cannabis manufacturer," "cannabis producer," "manufacture," and other terms do not match the definitions set out in statute. For example, "cannabis courier" in statute is a person "licensed" by DOH, whereas in regulation it is a person "approved" by the department. Likewise, "cannabis manufacturer" in statute is an entity "licensed" by DOH, whereas "manufacturer" in regulation is a person "approved." A "cannabis producer" in statute is "a person that is licensed by the department to possess, produce, dispense, distribute and manufacture cannabis and cannabis products and sell wholesale or by direct sale to qualified patients and primary caregivers," but a "licensed producer" in regulation is "a person or entity licensed to produce medical cannabis." "Manufacture" in statute means "to prepare a cannabis product," but "manufacture" in regulation means "to make or otherwise produce cannabis-derived product or concentrate."

The statute contains definitions for "cannabis establishment," "cannabis product," "cannabis testing facility," "hemp," "license," "licensee," "produce," and others, but the regulations do not contain these definitions.

As DOH knows, the issue of DOH's regulatory authority has arisen several times in litigation regarding the proper implementation of the Compassionate Use Act. When DOH uses different definitions than the statute does, the difference spreads confusion among medical cannabis businesses and patients. The differences also breed an atmosphere of distrust between medical cannabis business and DOH, because the businesses cannot serve two masters—both the statute and the regulation.

It is both legally proper and beneficial to the business-DOH relationship to ensure that regulations match statutory language. It is beneficial to the business-DOH relationship because it creates consistent standards and eliminates confusion. It is legally proper because "When an agency construes a statute that governs it, the court will accord some deference to the agency's interpretation," but "we are less likely to defer to an agency's interpretation of the relevant statute if the statute is clear and unambiguous, as it is in this case," and "if statutory construction is not within the agency's expertise, this Court should afford little, if any, deference to the agency on issues of statutory construction." *Marbob Energy Corp. v. New Mexico Oil Conservation Commission*, 2009-NMSC-013, ¶ 6-7, 206 P.3d 135. Additionally, between a statute and a regulation, the statute trumps the regulation. "When a statute and a regulation conflict, the statute prevails." *Gallegos v. State Bd. of Education*, 1997-NMCA-040, ¶ 23, 123 N.M. 362.

Certainly, DOH may add more definitions to its regulations than appear in statute. However, DOH's attempts to change the explicit wording of the statute is improper and inexplicable. The regulatory definitions should exactly match any definition given by statute.

NMAC 7.34.4.8(Z); Geographical Regions

This part of the proposed regulations states, "The department may additionally restrict the licensing of non-profit producers to applicants that commit to production and distribution of usable cannabis in specific geographical locations of the state."

Commenter Ultra Health believes strongly in serving rural areas of New Mexico, and for that reason, Ultra Health has opened dispensaries in 13 of out 33 counties in New Mexico.

Although DOH certainly expresses the right sentiment with this proposed regulation, its effect is unfortunately ambiguous. It is not clear whether this "restriction" applies to *new applicants* for a license or *applicants for re-licensure*. That is, will DOH consider the commitment to underserved areas only for applicants seeking entirely new licenses, or will DOH consider the commitment when it re-licenses entities who have held licenses for years? If DOH applies this criterion to already-licensed entities who are going through re-licensure processes, this criterion could result in closure of smaller producers and could disrupt production and patient access.

Additionally, the placement of this proposed regulation is odd. NMAC 7.34.4.8(F) already sets out "factors considered" in "determining the number of licenses" and which entities shall be licensed. If DOH is concerned about applicants' commitments to underserved areas, then it could add that as a "factor considered" in granting license applications in the first place.

NMAC 7.34.4.9; Minimum Standards for Production

Commenter Ultra Health believes the sentiment expressed by NMAC 7.34.4.9 is correct, but the vagueness of some of the provisions here will result in unworkable standards. Ultra Health believes that the general level of professionalism in New Mexico's medical cannabis industry should be increased, and Ultra Health believes that cannabis businesses should strive for high levels of quality control and technical accomplishment.

However, the level of strictness of 7.34.4.9 is positively draconian and may very well drive smaller producers out of business due to the costs of compliance. For example, 7.34.4.9(A)(1) requires compliance with "zoning, occupancy, licensing, and building codes." Many producers in New Mexico rent their premises and have little control over building codes. Placing the burden on producers means producers will have to spend significant sums on building code reviews and renovations in rented premises.

There are also vagaries that produce absurd results. For example, the requirement that all "equipment, implements, and fixtures shall be used exclusively for the production of cannabis" means that a microwave in an employee break room would be disallowed, and that the computer used to run BioTrack is disallowed. One provision here requires production to be conducted "in a manner that does not allow cross-contamination from chemical or biological hazards," without a precise definition of "hazards." Such innocuous substances as water or oxygen can quickly become hazards under specific conditions.

NMAC 7.34.4.9(A)(12)

One particularly problematic provision is NMAC 7.34.4.9(A)(12), requiring that "floors, walls, and ceilings are constructed in such a manner that they are washable, wipeable, and non-absorbent, and can be kept clean, and kept in good repair." This requirement is simply unworkable for the medical cannabis industry. It seems to have come from a food manufacturing setting, but DOH forgets that a medical cannabis facility combines an agricultural operation with a manufacturing operation.

Some producers still grow outdoors, in soil, and soil can never be made non-absorbent. Outdoor growers are also quite incapable of having "washable" ceilings, in that their ceiling is simply open sky.

Ultra Health itself grows in greenhouses with floors made of gravel; the purpose of the gravel is to allow excess water to flow away. The alternative—a non-absorbent floor—would mean that the plants are watered, and the excess water simply stands in pools on concrete. Standing water is a much more dangerous breeding ground for contaminants than gravel is.

If Ultra Health is made to renovate its greenhouses with non-absorbent flooring, it will have to pour concrete on the floor of the greenhouses; this will put the greenhouses out of operation for quite some time. It will also require Ultra Health to change its growing systems to install some method for drainage, so that water will not pool on the concrete floor. This will be another investment and will also take the greenhouses out of operation for a significant period.

Ultra Health understands DOH's purpose with this requirement: to ensure cleanliness. However, DOH must remember that cannabis is, first and foremost, an agricultural product grown in agricultural conditions. The manufacturing side is more akin to the food production field, from which DOH obviously took these regulations.

DOH must separate the growing from the processing and finishing. The growing stages should be subject to agricultural standards, while the processing and finishing should be subject to manufacturing standards. DOH has combined the strictest part of both worlds, and in doing so, has jeopardized the very existence of many producers.

NMAC 7.34.4.9(A)(3)

This provision requires a producer to ensure "that no cannabis plants other than those grown pursuant to the non-profit producer's production license from the department are grown on the premises of the non-profit producer, including but not limited to hemp plants."

This provision effectively prohibits a producer from co-housing medical cannabis plants and industrial hemp plants on the same campus. Now, the first problem here is one of vagueness: what is a "premises?" Are premises defined by the address of a property? By who owns which parcel of an addressed property? By fences? By walls?

The larger problem is that DOH exceeds its statutory authority by claiming power to regulate the location of hemp. When the Legislature legalized the cultivation of industrial hemp, it gave regulatory authority over hemp to the Department of Agriculture. See NMSA 1978 § 76-24-2 (2017). The Department of Health, on the other hand, has never been given any kind of regulatory authority over hemp.

DOH is now attempting to regulate the locations where hemp may be grown, and in doing so, DOH is usurping the regulatory authority of the Department of Agriculture. DOH can exercise limited control over where medical cannabis may be grown, but it cannot exercise control over where hemp is grown.

Furthermore, the limited ability of DOH to control where medical cannabis is grown does not include placing restrictions on what other crops may be grown alongside medical cannabis. NMSA 1978 § 26-2B-7(A)(6) provides that "production facilities" must be "housed on secured grounds and operated by licensees" and that other facilities must be "not within three hundred feet of any school, church or daycare center."

Now, as DOH will recall, Ultra Health obtained a writ of mandamus from the Thirteenth Judicial District Court in case D-1329-CV-2018-01854. That writ held that DOH could not place location restrictions on dispensaries other than the 300-feet rule. In a larger sense, the writ stands for the proposition that DOH cannot restrict land use of producers in a manner not set out in statute.

Here, statute sets out that production facilities must be secure, but it does not otherwise restrict how producers use their property. The statute does not specify indoor or outdoor grows, does not require labeling of the property to passers-by, and does not prohibit colocation of other activities.

Ultra Health believes that DOH, by prohibiting colocation of hemp and medical cannabis, is going beyond the bounds of statute. Now, Ultra Health would not oppose a regulation that

required reasonable segregation of hemp and medical cannabis within a premises or campus, such as with walls, fences, and signage. This type of segregation would be done only to ensure that the respective regulators of DOH and DOA could tell the plants apart.

NMAC 7.34.4.10; Testing

Once again, Ultra Health applauds the sentiment of NMAC 7.34.4.10—to increase the quality of medical cannabis produced in New Mexico—but must express serious reservations with the rule based upon potentially devastating effects.

Impossibility of Testing

The rule requires much more testing than is currently required. Currently, there are one-and-a-half laboratories in New Mexico that handle medical cannabis. Ultra Health says "half" of a laboratory because Scepter Lab laboratory is located in Santa Fe. The other laboratory, Rio Grande Analytics, is located in Las Cruces. It has been Ultra Health's experience that when couriers travel with medical cannabis to Las Cruces, federal Immigration and Customs Enforcement agents at the checkpoint in Las Cruces often take the cannabis and never return it.

If Scepter Lab shuts down entirely or shuts down partially, producers will have to rely on the laboratory in Las Cruces, and that will result in a high likelihood of federal agents taking the cannabis, thus preventing a test and disrupting the entire supply chain. Relying on the Las Cruces laboratory works well for producers who grow their plants south of the checkpoint at Las Cruces, but producers growing in central or northern New Mexico cannot rely on sending samples to Las Cruces knowing that they may be taken by federal agents.

Furthermore, DOH's new proposed regulations set much more stringent standards for many items than are currently in place. Ultra Health and the other producers do not even know if the laboratories are capable of testing to this level of specificity. Testing to these standards may require new and expensive equipment, with the result that no producer can pass the tests because no laboratory can do the test.

Additionally, it is not apparent that the existing laboratories can handle the volume of testing that will be required once plant counts increase. As DOH knows, the plant limitation has recently been raised from 450 to 1,750. Now, at 450 plants, Ultra Health was doing 400 batch sample tests per month. Ultra Health estimates it will be doing 2,000-3,000 tests per month at 1,750 plants.

Now, NMAC 7.34.4.10(A) does provide that DOH may waive testing if laboratories are not able to perform the tests. However, mere ability should not be the only factor in waiving testing requirements. A laboratory may have the *ability*, but the test may 1) take so long; or 2) cost so much, that the result is delayed product or product too expensive for patients. DOH, in focusing on laboratories' ability, ignores a holistic view of the market. What good is a product subject to the most rigorous tests if it ends up being too expensive for patients and takes too long to obtain? DOH states its purpose in implementing these rules is to ensure "beneficial use," as is

the purpose of the Compassionate Use Act. A product that is too expensive or takes too long to get is not "beneficial."

DOH Does Not Know if Producers Will Be Able to Meet the Standards

Another glaring problem with NMAC 7.34.4.10 is that DOH has no idea if most producers will be able to meet the requirements at a reasonable rate. DOH of course must have testing requirements, but it must balance stringency of testing requirements with overall health of the market. If 95% of products fail the most stringent of testing requirements, is that acceptable to DOH and to patients? If 10% of products fail, is that acceptable?

DOH should adopt a pilot program to test the test—to find out if these are workable standards. Indeed, the standards proposed by DOH are as strict or stricter than those of many other states, including states that have had robust and well-supported programs for much longer than New Mexico has. See, for example, the testing requirements of California and Colorado, attached here.

Incidentally, stricter testing standards in Colorado and California have had negative effects on those states' legal programs, as higher testing expenses are passed on to the consumer and consumers go to the black market instead of staying within the legal market. DOH should look to the negative experiences of these states and ask if lowering a standard by a few parts per million is worth sick patients going to the illegal market to obtain cannabis.

A pilot program, under which the stricter testing is done but the current testing is enforced, would be useful in demonstrating to DOH if the stricter testing mode is necessary or achievable. The pilot program could also provide an indicator on how testing influences black market infiltration—will consumers pay the extra price and wait longer for legal products, or will they return to the black market?

DOH Has Failed to Consult the Medical Advisory Board

Now, Ultra Health itself does have a very rigorous quality control program that influences production practices from seed to sale, and Ultra Health believes very strongly in placing patients' safety above all else. However, it does not seem that DOH has actually consulted the Medical Advisory Board about the proposed testing standards in order to determine if they truly improve patient health.

The Medical Advisory Board is created by statute, NMSA 1978 § 26-2B-6 (2019). The statute creating the Medical Advisory Board does not explicitly say DOH must consult it regarding testing requirements, but given the Board's existence, it would seem strange *not to consult* it on these testing standards. The Board exists to provide professional advice to DOH on the management of the Medical Cannabis Program, and testing standards is right up the Board's proverbial alley.

Indeed, it seems arbitrary, capricious, and absurd for DOH to promulgate rules on safety standards for medical cannabis without consulting the Medical Advisory Board. The Board

should have been consulted to determine 1) if the current supply of medical cannabis from licensed entities is not safe enough; 2) if legal sources of medical cannabis were sickening patients at unacceptable rates; 3) if more stringent testing standards would improve safety; 4) if the testing standards were properly balanced against other negative effects, such as increased price and decreased supply.

The failure of DOH to obtain the advice of the Medical Advisory Board regarding testing standards indicates DOH's promulgated standards are arbitrary, capricious, and simply plucked from the air, rather than being the product of scientific consensus.

More Stringent Standards Will Decrease Supply

It also appears DOH has failed to consider how more stringent testing will impact supply. First, there is the impact of the sampling size. The new rules require batch testing and require "off-the-shelf" testing (see 7.34.4.10(C)(6), "Random testing of finished cannabis derived products). Ultra Health calculates that all testing combined will consume one half-pound of every five-pound batch. And of course, the testing called for by DOH is, by its nature, destructive testing—the test destroys the cannabis.

This means 10% of harvested cannabis will be consumed by testing alone. In turn, this means 10% of supply goes to testing rather to patients. If DOH truly wishes to require that much testing, it must adjust the plant count to make up for the material lost to testing.

Additionally, more stringent standards will lead to higher failure rates, and higher failure rates will mean more cannabis is destroyed than goes to patients. Cannabis that does not pass tests and cannot be remediated will be destroyed. The more cannabis destroyed is more cannabis that cannot serve patients.

In this way, more stringent standards drive down supply. If DOH wishes to tighten testing standards, it must know that this will negatively affect supply. The loss to testing failure must be made up with an increase to the plant count.

When DOH calculated patient demand in the spring of 2019, it did so without calculating the amounts lost to failed tests. That is, it calculated the amount of cannabis "sufficient" to meet patient needs in an imaginary, perfect world where no cannabis ever failed tests. However, this is not a perfect world, and if 25% of cannabis fails tests and is un-saleable, the plant count limitation must be adjusted up by 25% to account for that loss.

This shows, yet again, that managing a medical cannabis market requires balancing different factors. It is highly unlikely that DOH can achieve a working market with both high testing standards and low plant limitations. It would be more likely to achieve a working market with high testing standards and high plant limitations, or lower standards and lower limitations.

To use a popular colloquialism, DOH wants to have its cake and eat it too: it wants to keep plant counts too low to account for plant material lost to failures of stringent testing

standards. These testing standards will only result in decreased supply, higher prices, and more patients being driven to the black market.

The Standards Will Result in Producers Closing Their Businesses or Selling Licenses

Ultra Health predicts that instituting uniformly stringent testing standards, without a period for adjustment and without an indication that patient safety is currently compromised, will result in smaller producers closing their businesses or selling licenses to out-of-state interests.

Some producers will simply not have the wherewithal to achieve more stringent standards. The cost of improving their techniques will be very high, and lack of access to capital will prevent them from instituting capital improvements. This will then result in a markedly reduced output or closure of the business entirely. Additionally, current licensees will look to out-of-state interests to buy licenses. This would set a bidding war that does not serve the interests of New Mexico patients.

Currently, both large and small licensed producers face a litany of challenges to the survival of their businesses: 1) the punitively high licensing fees demanded by DOH; 2) punitive tax treatment that results in very large tax burdens; 3) lack of access to capital because of restrictive federal laws; 4) constant competition from the black market; 5) high costs of production because of high energy and water costs. On top of this, DOH adds stringent testing standards that could result in failure rates as high as 95%. In this antagonistic atmosphere, producers could simply start closing.

NMAC 7.34.4.10(E)(5)

NMAC 7.34.4.10(E)(5) provides, "repeated failure to pass testing may result in the imposition of disciplinary action(s) by the department, consistent with this rule."

DOH does not give any indication of what it considers to be "repeated." As stated above, Ultra Health plans to conduct 2,000 to 3,000 tests per month. Of course, there will be repeated failures given this high number of tests. This begs the question of whether two failures will subject a producer to disciplinary action, and certainly, every single producer will have more than two failures.

The producers and manufacturers need to know what DOH considers to be an unacceptable number or percentage of testing failures. When coming to those numbers, DOH should consider that the medical cannabis industry is different in important ways from pharmaceutical manufacturing or food manufacturing. Pharmaceutical manufacturing deals with often inert chemicals, but cannabis producers must deal with a living plant that has all the complexities of a living being.

The variability and failure rate of, say, bread will naturally be different from the failure rate of, say, Coca-Cola, given that bread is made with living microbes (yeast) and Coca-Cola is made from inert sugar. Likewise, the variability and failure rate of cannabis products will be

higher than other medicinal products because of the simple fact that cannabis plants are living beings that respond to their environments.

Ultra Health asks that DOH consult with the Medical Advisory Board to come forth with proposals for unacceptable rates of testing failures, with special attention paid to the context of medical cannabis cultivation.

Conclusion on Testing

The institution of more rigorous and stringent testing standards and protocols obviously derives from good intentions, but the new rules will result in more negative than positive consequences to the Medical Cannabis Program as a whole.

NMAC 7.34.4.14; Manufacturing Provisions

NMAC 7.34.4.14(B)(3) requires submission of a "hazard analysis critical control point plan" for each type of product manufactured. Again, it appears DOH has derived this requirement from food manufacturing regulations. HACCPs are in fact heavily regulated by the federal FDA, such that the FDA has an extensive article on HACCP guidelines on its website: https://www.fda.gov/food/hazard-analysis-critical-control-point-haccp/haccp-principles-application-guidelines

A recent study by the food industry found that developing a HACCP costs around $25,000 per product for "small establishments." See https://foodindustryexecutive.com/2017/02/how-much-food-safety-compliance-really-costs-for-meat-and-poultry-report/, also attached here.

Now, even if a manufacturer can afford to develop a HACCP plan, it is not apparent what expertise DOH has to judge it. That is, does DOH have employees with expertise in HACCP plans to know if a manufacturer has submitted a genuine one or simply a garbled collection of nonsense.

This is the difficulty in DOH attempting to regulate a subject matter more traditionally regulated by, say, the Department of Environment, or Regulation & Licensing. If DOH is to demand a HACCP, manufacturers must be assured that those plans will be evaluated by regulators with expertise in the area, and not by inexperienced DOH officials with no real training in food safety.

Again, DOH must balance the 1) perceived need for HACCPs; 2) the actual need for HACCPs; and 3) the burden on manufacturers. Some manufacturers will simply forgo HACCPs and stop manufacturing a particular product. Others may invest in HACCPs but will pass the cost onto patients, resulting in higher prices and flight to the black market.

The recent "vaping crisis" has resulted in increased focus on the safety of tobacco and cannabis products. However, the nexus between HACCPs and the vaping crisis is not apparent.

After all, the culprit in serious "vaping" illnesses has been found to be Vitamin E acetate, and DOH's proposed regulations altogether ban the use of Vitamin E acetate.

This shows that DOH can create targeted regulations that reach specific dangers without having to place vague and expensive regulatory burdens on businesses. The specific prohibition on Vitamin E acetate is a reasonable, targeted mechanism designed to specifically reduce one very specific harm at almost no cost to manufacturers. On the other hand, demanding HACCPs is a very onerous burden whose broad reach is not designed to target a specific problem.

Furthermore, the recent "vaping crisis" has proven once again the danger of illicit and illegal sources of cannabis. DOH can most immediately protect the health of New Mexicans by encouraging use of legal sources of cannabis and discouraging illegal sources. Forcing legal manufacturers to raise prices will only discourage legal access and encourage illegal sales.

Again, Ultra Health must ask if the Medical Advisory Board recommended HACCPs or sees a need for them. Ultra Health does not know if DOH has been inundated by patient complaints recently, but if DOH has, it should inform producers and manufacturers so that businesses can make targeted improvements. A HACCP requirement, without evidence of a broad spectrum of patient complaints, is like using a bulldozer to kill a mosquito. Rather, DOH and manufacturers should work together to find specific solutions to specific problems.

NMAC 7.34.4.14(C) Conflates "Additive" and "Addictive"

NMAC 7.34.4.14(C) is titled "prohibited additives" and then states manufacturers shall not "combine nicotine, caffeine, or any other addictive substance" with cannabis. This seems to conflate "additive" with "addictive."

The word "addictive" is not useful if it is not defined. First and foremost, sugar is now considered an addictive substance by many medical professionals. Read broadly, this rule would prohibit the combination of sugar with cannabis, and would therefore ban such products as cannabis gummies, cannabis hard candies, cannabis cookies, cannabis brownies, cannabis lollipops, etc. Prohibiting the use of sugar would decimate the market for edible products.

Ultra Health agrees that certain substances should not be combined with cannabis, but it asks for a specific list given that "addictive" could very well apply to sugar.

NMAC 7.34.4.27; Reciprocity

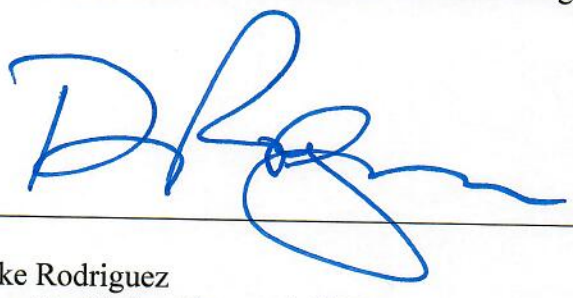
Ultra Health notes several ambiguities in the provisions regarding reciprocal participation and requests DOH clarify these points so that the reciprocal program may be implemented smoothly.

The rule requires participants to "register with a licensed non-profit producer." Ultra Health assumes this means out-of-state visitors can register with multiple producers and is not restricted to one.

Ultra Health also assumes that this "registration" will be visible to all producers, because all producers must be able to see a person's purchase history in order to ensure that the person does not purchase greater than 230 units within a 90-day period.

CONCLUSION

Ultra Health requests the Department review these comments in the context of improving the overall health of the Medical Cannabis Program to ensure its long-term success.



Duke Rodriguez
Ultra Health President and CEO

SUBMITTED: January 15, 2020

[EXT] Public Comment

[redacted]

Thu 1/16/2020 7:48 AM

To: comment, MCP, DOH <MCP.Comment@state.nm.us>;

Good Morning,

My name is [redacted] and I am a medical cannabis patients both here in the state of New Mexico and the state of California. I am writing today with concerns of certain rules in the program. These concerns I feel are I will address need to be resolved immediately and accordingly.

1. Testing for our state program is horrendous. Test samples can easily be manipulated by the grower. Surprise visits to selects samples by a state representative and or third party collector should be done. Also complete testing is a must! Heavy Metals, pesticides and compete microbial panels must be done. This is needed for the safety and health of our patients. Every Licensed Non Profit should also be randomly and surprised evaluated both at retail locations, manufacturing and growing locations to ensure all protocols, SOP's and state requirements are being complied with.
2. Open up licenses and or create a micro license which will allow small craft growers and PPL growers to provide their excess medicine to authorized locations for patients to purchase. With the plant count going up quality has significantly gone down. Out of there entire state only 2 shops are worth my dollar and time. That is Sandia Botanicals and The Harvest Foundation. All the other 10 LNPP's in the state produce either poor quality or poor quality at a high price. This forces us to the Black Market as we can find better medicine quality at a better affordable price. Please open up licenses and save our program.
3. Consumption sites should not be limited to LNPP's. Especially in southern New Mexico where locations are scarce and few and far between. If I don't buy my medicine there why would I go there to medicate? Patients should have the options and availability to choose a location that is neutral and comfortable outside and away from the retail locations. It's almost as if you're forcing us to by this medicine in order to be able to consume at these site if they are located at retail shops.
4. Unit limit needs to be removed and follow along the lines of California Medical limits. All of us patients medicate differently. Some require different types of medication. Limiting our medication forces a lot of us to go Black Market. Most of us reach our 3 month limit in a month. Leaving us either with out medication for 2 months or forcing us to go to the streets. As a patient I should be able to walk into a retail location and purchase 8oz of cannabis flower so I may process canna butter for cooking. Also gift to other patients who may need it. This alone already uses my entire limit and will force me to go blackmarket. Please remove this limitation and stop supporting the black market and allowing it to thrive.

Thank you for your time and consideration,
[redacted]

[EXT] Please Open up licenses

[redacted]

Thu 1/16/2020 7:48 AM

To:comment, MCP, DOH <MCP.Comment@state.nm.us>;

I'm tired of travelling 80 min round trips to find shelves empty & bad flower... Please allow PPL to test flower and help fill shelves at all local Medical dispensaries

Sent from Yahoo Mail on Android

[EXT] Comments on MCP Rules

Jason Marks, Esq. <lawoffice@jasonmarks.com>

Thu 1/16/2020 8:53 AM

To: comment, MCP, DOH <MCP.Comment@state.nm.us>;

1 attachment

JML Comment 2020-01-16.pdf;

Dear Andrea:

Please see attached. Best wishes,

Jason Marks

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January 16, 2020

Ms. Andrea Sundberg
NM Department of Health
Medical Cannabis Program
P.O. Box 26110
Santa Fe, NM 87502-6110 *via email to MCP.comment@state.nm.us*

Comments on Proposed regulations at 7.34.4 NMAC

Dear Ms. Sundberg:

This letter is filed as public comment in response to the Department's Notice of Public Hearing on the repeal and replacement of MCP rules at 7.34.4 NMAC, which states a second public hearing to be held on January 16, 2020. I previously submitted the comments that following a letter dated and filed November 22, 2020. I was pleased that in the new version of the proposed rule, the Department corrected several of the problems that I noted in my initial round of comments. Some of the other apparent changes from the October draft appear to be beneficial as well. However, many serious problems remain in the proposed rule, particularly as concern very wasteful and unjustified testing requirements for heavy metals and aflatoxins, and the Department's plan to mandate specific testing equipment. These comments largely overlap the comments I filed on November 22, 2019, but have been updated to reflect renumbering and some additional information.

These comments are based on the knowledge and experience gained through providing legal representation to more than one-quarter of all the entities holding medical cannabis production licenses, or their affiliates, to the largest medical cannabis testing laboratory in New Mexico, and to licensed manufacturers and patients.

My specific comments follow:

1. The Department May Not Reserve the Power to Promulgate Ad Hoc Rules

The Department of Health may only promulgate rules affecting the entities it regulates by going through a formal rulemaking process with notice and comment, and publishing such rules in the Register and the Administrative Code. Yet, throughout the proposed 7.34.4 NMAC, the Department has purported to reserve to itself the power to create *ad hoc* regulations at its discretion, without going through notice and comment, or publication. This is not permitted by statute. The defective rules include (the following may not be an exhaustive list):

7.34.4.8(G)(4) "requiring additional relevant information as the department deems necessary"[1]

7.34.4.8(O)(14) "such other policies or procedures as the department may require."

7.34.4.14(B)(26) "such other materials as the department may require."

7.34.4.17(D)(11) "such other materials as the department may require."

7.34.4.22(I)(3) ". . .such other information as the department may reasonably request."

7.34.4.27(B)(12) "such additional information or materials as the department may require."

7.34.4.30(B)(3)(r) "Such additional information as the department may request."

The Department of Health's organic act provides that: "Unless otherwise provided by statute, no rule affecting any person or agency outside the department shall be adopted, amended or repealed without a public hearing on the proposed action before the secretary or a hearing officer designated by him." NMSA 1978 9-7-6(C). "The statutory designation for an enactment by an agency designed to have the force and effect of law and to control the actions of persons who are being regulated by the agency is a 'rule'." *Bokum Res. Corp. v. N.M. Water Quality Control Comm'n*, 1979-NMSC-090, ¶ 41; see also NMSA 1978 14-4-2(C) ("rule" is any regulation or standard purporting to affect persons not employees of a state agency).

In each of the instances listed above, the Department purports to claim the ability to control the conduct of regulated entities using standards that it has not published in a formal regulation. That is improper. While all the examples provided above are defective, the most egregious is 7.34.4.8(O)(14), by which the Department purports to reserve unlimited power to impose new regulations on LNPPs without going through rulemaking. These defective rules should be stricken, and the Department should promulgate regular and emergency rules, as needed, as regulatory concerns change.

2. The Department May Not Restrict Producers to Non-Profit Corporations

The LECUA, as amended by SB 406, authorizes the Department to license "cannabis producers." NMSA § 26-2B-3(G). A cannabis producer is "a person that is licensed by the department to possess, produce, dispense, distribute and manufacture cannabis and cannabis products and sell wholesale or by direct sale to qualified patients and primary caregivers." *Id.* (emphasis added). Elsewhere, the Legislature directed the Department

[1] I recommend that subpart G be replaced with "The department may verify information contained in each application and accompanying documentation by requiring supporting documentation or other reasonable means" and striking the subparts" and striking the numbered subparts. The department obviously needs the ability to verify information, but (G)(4) opens the door to the Department unlawfully changing the application requirements .

to issue licenses to "(1) cannabis couriers; (2) cannabis manufacturers; (3) cannabis producers; (4) cannabis testing facilities; and (5) any other activity or person as deemed necessary by the department." NMSA § 26-2B-6.1(D). The Department mostly complies with this in its proposed regulations by providing for the licensure of "couriers," "manufacturers," and "laboratories," but the Department doesn't license "producers." Instead, the Department has created a category of licensure different from the statute, the "non-profit producer."

The Department, under the authority of Section 26-2B-6.1(D)(5) could create the non-profit producer category, but only as an alternative to a generic "producer," which must be an entity that is a legal "person" of any type. This is required by the Uniform Statute and Rule Construction Act, which provides that the word "person" when used in statute, such as in the LECUA definition of "cannabis producer" *supra*, means "an individual, corporation, business trust, estate, trust, partnership, limited liability company, association, joint venture or any legal or commercial entity." NMSA 1978 § 12-2A-3(E).

In addition to being contrary to the Department's statutory authority, restricting producers to non-profit corporations is arbitrary and unjustified. Operation of a medical cannabis producer compliant with the Department's regulatory standards requires substantial capital investments. Nonprofit entities are unable to obtain capital as equity investments. The bank that has single-handedly made it possible for New Mexico cannabis businesses to have access to depository banking services since 2015 does not issue commercial loans to medical cannabis businesses. The ability of medical cannabis producers to obtain debt financing from private persons and entities who are related parties is very limited, and comes at a high cost.

In response to the Department's *ultra vires* and poorly conceived policy restricting producer licenses to nonprofit entities, for-profit affiliates of LNPPs have proliferated as a means of generating investment capital and incentivizing cost-effective operations. The economic effects of such affiliations are, in many cases, almost the same as if the license was held by a for-profit, but with a loss of transparency and diminished accountability. The Department is well aware of these arrangements, and routinely approves (or passes) on them. The Department's proposed regulations evidence the confusion, referring in places to the "owners" of nonprofit producers. Further, as the Department is aware, LNPPs receive none of the tax benefits of non-profit status.

For the preceding reasons, the Department should eliminate the restriction of producer licenses to non-profits and permit existing license holders to transfer licenses to their existing affiliates.

3. Application of the Three-Hundred Foot Limit Must Comport to Statute

The Legislature prohibited cannabis <u>distribution</u> activities within 300' of a school, church, or daycare center. NMSA § 26-2B-7(A)(6)(b). The Legislature did not extend the 300' requirement to production facilities, or for that matter to laboratories or manufacturers. For production facilities, the Legislature specified instead that they be on

"secured grounds." NMSA § 26-2B-7(A)(6)(a). Under the well known canon that, when the Legislature shows it knows how to enact a provision in one circumstance, but does not do so in another, legislative intent is that the Legislature did not intend that provision to apply where it was not specified.

Moreover, there are obvious reasons why the Legislature could have wanted to put a buffer between school children and preschoolers and the very public activities of retail cannabis distribution. There is no obvious or even plausible reason why production activities, which are not visible to persons outside of the building in which they are housed, would need to be placed a distance from schools and churches. The Department should change 7.34.4.8(F) to only apply the 300' restriction to producers' distribution facilities, to be consistent with statute, and remove it where it appears in the laboratory and manufacturer rules.

Lastly, the Department has previously stated that it interprets the location limits in the LECUA in the same manner as provided by the state's Liquor Control Act, NMSA § 60-3A-1 *et seq*. The Liquor Control Act, like the LECUA, only imposes location limits upon the sales of alcoholic beverage, not on their production: "No license shall be issued by the director *for the sale of alcoholic beverages* at a licensed premises . . . that is within three hundred feet of any church or school." NMSA § 60-6B-10 (emphasis added). But, unlike the Department of Health, the Regulation and Licensing Division does not attempt to exceed legislative intent and apply location limits to beverage production locations. *See* 15.10.32.8 NMAC (only applying 300' limit to locations where "where alcoholic beverages are proposed to be sold.")

4. Standards Necessitating License Amendment are Over-Broad

The proposed regulations at 7.34.4.8(R)(1)(b) and .17(J)(1)(a) require application license amendment by a producer or laboratory upon "any physical modification or addition to the facility." This is an arbitrary and over-broad standard bearing no relation to any legitimate regulatory concerns. Under the plain language of the regulation, a licensee would be required to go through a costly and time-consuming amendment process any time it adds lighting, changes flooring or surfaces, reconfigures a back office or break room, or makes any number of possible physical modifications that have no effect on security or other regulatory concerns. These regulations should be re-written to require amendment only for physical modifications that add or removes space to areas where cannabis is dispensed, stored, or produced; or that change the location of external doors; or which materially changes the security system.

The proposed regulations at 7.34.4.8(R)(1)(b) and .17(J) also require amendment upon the change in ownership of facilities. Transfers in building ownership by the third-party, arms-length landlord of a cannabis business has no regulatory import and should not require a filing by the business. This requirement appears to come from the Department's concerns about disclosure of the identity of related parties to cannabis businesses. The Department should make a related party rule to focus on the circumstances with which it actually interested, and eliminate rules like these that burden

licensees engaged in standard business practices with arms-length third parties. Similarly, licensees should not be required to disclose all persons with indirect interest in facility ownership, whose identities may not be known to them in the context of an arms-length lease.

The proposed regulations at 7.34.4.8(R)(1)(b) requiring amendment for changes in LNPP directors is also excessive and burdensome to the ordinary course of business for LNPPs, in which directors resign without notice or must be replaced immediately for other reasons. Moreover, other rules already require background checks and issuance of an employee card for new directors. The Department's additional needs to know about director changes could be satisfied by a notice requirement.

5. Issues with Laboratory Testing Requirements

a. Microbiological Testing Requirements/Action Levels are Excessive

The Department has specified action levels for microbiologicals that exceed what some other states require. Over-regulation in microbiological testing adds unnecessary costs for production activities and remediation. Unnecessary remediation can also adversely impact cannabis medicine.

The recommendations from the Cannabis Safety Institute white paper should be adopted, which also comport with the extensive experience of Scepter with respect to samples which have failed microbiological screening, for which the lab often engages in follow-up investigations:

1. Cannabis should be tested for four species of Aspergillus: A. flavus, A. fumigatus, A. niger and A. terreus. Together these species are responsible for the vast majority of cases of invasive pulmonary aspergllosis and they are the only pathogens that represent a clear and certain danger on cannabis.

2. Cannabis should be tested for total generic E. coli. Samples with levels above 100 cfu/gram should be rejected. This is the one indicator test that we recommend. Detection of significant levels of E. coli are strong evidence of problems during growing or processing. E. coli is now accepted to be the optimal indicator organism for the identification of possible fecal contamination. Were pathogenic bacteria to be present, they would likely have arrived through this type of pathway, therefore samples positive for E. coli are indicative of general production problems that need to be addressed.

3. Cannabis should be tested for Salmonella. The odds of salmonella infection from cannabis are very low. Nonetheless, it is the one bacterial pathogen that poses a potential threat to cannabis smokers. There is precedent for salmonella association with cannabis. It is highly infectious

and can cause disease with as low a dose as one single cell. It is hardy and resistant to dessication.

4. Testing cannabis for total yeast and mold is unnecessary and unjustified. Total yeast and mold tests detect only a small fraction of the fungal species in the environment, and do not correlate with the presence of pathogenic species. The only pathogenic mold species on Cannabis are types of Aspergillus that should be tested for separately. Molds can potentially be a cause of allergic hypersensitivity reactions, but there is no evidence that these are mediated by smoking. In the alternative, the combined total yeast and mold count action level should be relaxed, as it is not indicative of health risks, and is often triggered by the presence of benign yeasts.

b. Routine Mycotoxin Testing Should be Eliminated

As of this fall, Scepter Lab had conducted 15,649 mycotoxin tests on medical cannabis samples since the requirement was implemented in NM, at a cost to producers of $704,205,00, without registering a single positive result. To our knowledge, there has not been a single positive mycotoxin test result by any NM cannabis laboratory. Confident Cannabis, a company providing a popular cannabis laboratory software platform, says its records only show about 100 positive results for mycotoxins across all of its client laboratories, and none arising from activities in dry climates like ours. Confident Cannabis states that it has a 40% market share of labs across the U.S. and Canada.

Kathleen O'Dea, who has advanced credentials in microbiology and has worked in microbiology outside the cannabis industry as well as operating Scepter, has reviewed the scientific literature and concluded that mycotoxins are rarely found in cannabis because the material does not support the growth of the organisms that produce mycotoxins or the production of mycotoxins. The Cannabis Safety Institute states that "seedless cannabis plants are not capable of supporting aflatoxin production, because they lack the high oil content necessary for replication."

Moreover, The Cannabis Safety Institute also finds that "Aflatoxins will degrade by the heat of smoking or decarboxylation, if any were present."

On November 12, 2019, Kathleen O'Dea requested that Department of Health produce all materials in the possession of Scientific Laboratories Division (SLD) justifying routine mycotoxin testing in medical cannabis. As of the filing of these comments, two months later, the Department has not been able to produce any such documentation.

A requirement for routine mycotoxin testing, at very material expense, is arbitrary and capricious and not supported by any reasonable assessment of risks.

c. Routine Heavy Metal Testing is Unjustified

The route by which heavy metals can potentially contaminate medical cannabis is through the soil or water used to grow the plants.[2] The Cannabis Safety Institute only recommends heavy metal testing where cannabis is grown outdoors on land where there has been historical use of arsenic based pesticides that has accumulated in the soil. (Arsenic-based pesticides are today banned in the U.S.)

To my knowledge, all medical cannabis cultivated indoors in our state is grown in media obtained or produced from commercial products marketed for this purpose. All of the medical cannabis I have seen being grown outdoors in New Mexico has also been grown in such media, in containers, and not in the native soil. The MCP, which has visited all outdoor production sites, can verify that cannabis is rarely, if ever, grown in native soil.

Indoor cannabis is mostly grown using regulated municipal or other utility water supplies. Regardless of source, producers typically use advanced filtration to purify water of any contaminants prior to applying to their plants. Thus, even unregulated water supplies do not present a safety risk if adequate water filtration and treatment is in use.

It is not possible for cannabis grown in commercial growing media using water from a regulated source to become contaminated with heavy metals. It is arbitrary and unjustified for the Department to require routine heavy metal testing, which will impose very significant expenses on the testing laboratories and on the producers, in the absence of any plausible risk. Scepter estimates the cost of the equipment necessary to implement heavy metal testing will be well in excess of $100,000 to purchase or at least $30,000/mo to lease.

A reasonable rule that protects patients from heavy metal-contaminated medicine would target soil and unregulated wells, not the cannabis. The Department could (and should) require any producer proposing to grow in native soil to have that soil tested for heavy metals before the production area is licensed. Similarly, the Department could require proof of testing for water supplies which come from an unregulated source. Such soil and water testing, would not involve any cannabis, and thus could be provided by any accredited laboratory. It would only need to be done once, prior to beginning to use the soil or water supply.

On November 12, 2019, Kathleen O'Dea requested that Department produce all materials in the possession of SLD justifying routine heavy metals testing in medical cannabis. As of the filing of these comments, two months later, we have not received any such documentation.

d. Pesticide Testing Should be Refined

The Department's regulations permit the use of any licensed pesticide, but require testing

[2] Assoc. of Public Health Laboratories, *Guidance for State Medical Cannabis Testing Programs*, May 2016, at page 26.

for only 13 substances. This is both too many and too few. Too many, when it is wasteful to require testing for substances that have not been used in the cultivation of a particular batch of cannabis, and too few, when the rules allow the use of substances that will not be tested for. The Department is justified in seeking to prevent patients from being exposed to pesticide residues, but the proposed rules are not well-tailored to this end.

In addition, the equipment and supplies to implement pesticide testing are expensive to obtain. The list price for the equipment is $450,000. It is not possible to economically amortize an upfront cost like that over the volume of testing samples in New Mexico. Scepter estimates it will need to charge $250 per sample for pesticide testing.

The Department should withdraw the pesticide testing rule and convene a work group of patients, producers, and testing laboratories to arrive at a workable rule.

e. Requiring Specific Testing Technologies and Samples is Unjustified

The proposed rules mandate that laboratories use certain technologies for required tests (Table 7). This is arbitrary and unjustified. The Department has a legitimate regulatory interest in assuring that testing is performed accurately. But laboratories should be permitted to utilize any technology that can demonstrate sufficient testing accuracy. By mandating specific technologies, the Department may require a laboratory to incur unnecessary costs to replace equipment that is functional, and will certainly discourage innovation that can lead to greater testing efficiency.

In a specific example of how this mandate is unjustified, Scepter currently uses the ELISA method for detecting mycotoxins. This method is fully validated for use in cannabis and generates numerical data that "matches" with HPLC. Scepter has been validated by NMDOH and its Scientific Laboratories Division as being capable of producing accurate results in mycotoxin testing using its current method. Other states allow the ELISA method.

The first steps in the ELISA method are procedurally identical to the HPLC method. The only difference is how the active material is “read" - HPLC or spectrophotometer. From interaction with DOH’s Scientific Laboratories Division, Scepter knows that it prefers the HPLC, but there is nothing "wrong" or "invalid" with the ELISA method. It would be a significant hardship and expense for Scepter replace its spectrophotometers with a new detector for its HPLC machine, and it would take months of validation studies to bring this on-line. Mandating certain methods and rejecting others which are completely functionally equivalent is the textbook definition of “arbitrary” government conduct.

On November 12, 2019, Kathleen O’Dea requested that Department of Health produce all materials in the possession of Scientific Laboratories Division (SLD) justifying the proposed prohibition on use of ELISA for mycotoxin testing in medical cannabis. The Department produced documentation indicating from one manufacturer that indicated the ELISA method could not differentiate between Aflatoxin B_1, B_2, G_1, and G_2, or between

Orchratoxins A, B, and C. SLD concluded that ELISA is a qualitative test for the presence of mycotoxins, but not good at measuring the various mycotoxin variants.

However, even if the preceding is true, the Department's proposed Action Level standard is based on a combined concentration of all tested-for mycotoxins. When myctoxin contamination of medical cannabis is unknown in New Mexico, and ELISA is capable of identifying the presence of toxic contaminants if they ever do appear in a sample, it is unjustified to require a different testing method solely to provide more accurate data by mycotoxin variant. I.e, according to the Department's own approach, it is not necessary to know the precise concentration of each variant to identify a sample as unsafe for patient use. At-worst, ELISA testing might generate false positives based on orchratoxin variants that are not part of the Department's screens.

Next, the Department should also not mandate specific sample quantities in rule. There is no plausible reason for doing so. Sample sizes should be what is determined by the testing laboratory to be necessary for it to provide complete and reliable results. Any amount in excess of this is effectively an unnecessary expense to producers, and serves to increase the cost of medicine to patients. Mandating excess sample sizes, like all regulations that increase testing costs, incentivizes producers to find ways to test less, which is ultimately contrary to the objectives for the testing regulations. If the Department wants to provide assurance to producers that it won't require inordinate amounts of cannabis for its own "quality assurance testing," then it can make the quantities in its Table 7 specific to that purpose.

f. "Quality Assurance Testing" is of Limited Value

The Department proposes to test, or obtain tests of, cannabis and CDPs it obtains from producers and manufacturers in 7.34.4.12. The results of such testing are not indicative of the testing accuracy of laboratories which may have tested a sample from the batch which is now being examined by the Department, nor are such results indicative of anything other than how that singular, individual product tests. Cannabis is biological material and will differ by as much as 30% from the top of the plant to the bottom or from plant to plant. That portions of a harvest may be exposed to different conditions during drying, curing, and other processing also introduces non-uniformity.

g. End Product Testing is Unjustified

The Cannabis Safety Institute recommends against end-product testing of cannabis edibles (food products), and recommends instead requiring production under sanitary conditions, which the Department elsewhere does in its rules. *Microbiological Safety Testing of Cannabis*, Cannabis Safety Institute, May 2015. This approach follows the best practices in the production of commercial foodstuffs. Cannabis Safety Institute states:

> Cannabis food products are as likely to become contaminated as any other processed or prepared commercial food product. But because of its unique attributes, Cannabis is the least likely component to be the source of contamination in any food product.

> [emphasis in the original.] Cannabis is present in foods as an extract of the plant material. This plant material is dried to a safe level before extraction. And then either during or after extraction it is usually subject to a decarboxylation process that serves as a heat-kill step. The vast majority of the extraction processes are themselves sterilizing. Once these extracts are added to food, the food can always be mishandled or subject to "temperature abuse", which raises the chances of contamination. But these are factors facing all foods, and the only pathogen of real concern on Cannabis (Aspergillus) is not infectious by the oral route. Cannabis food products should be regulated as all food products are . . .

h. Repeat "Initial Demonstrations of Capability" are Unjustified

The proposed rules at 7.34.4.19(F) require an Initial Demonstration of Capability (IDC) or Continuing Demonstration of Capability (CDC) whenever a laboratory is initially approved for a platform, for each annual renewal, or when equipment is moved, or a new instrument installed. In revising the October 2019 proposed rules, the Department created the new definition of a CDC, presumably to acknowledge that IDCs for license renewals are not "initial." But this is just a fix at the level of semantics, when a CDC is the same as an IDC, the Department is continuing its misguided approach of requiring expensive and unnecessary repetition of something that has already been demonstrated.

"Initial Demonstration of Capability" means just that – an initial demonstration. It is reasonable for NMDOH to require a laboratory to prove that it can perform testing using a particular platform with accuracy, and under a range of concentrations, prior to approving the lab for that platform. An IDC is a demonstration that a laboratory has the basic capabilities, which are testing machines and other equipment, consumables, and standard operating procedures, to test with accuracy using a platform. If the laboratory is not changing any of these parameters, then there is no reason to require another initial demonstration (or the equivalent in a CDC). In satisfying an IDC, a laboratory makes a focused effort to produce specific demonstrations outside of its normal commercial operations. Thus, a redundant IDC/CDC has no real value in demonstrating the accuracy of a laboratory's routine operations. Scepter's experience, which comports with common sense, is that once a laboratory has developed the ability to satisfy an IDC requirement for a platform, it can always replicate that showing, given sufficient expenditure of time and money. Redundant IDC/CDC requirements are effectively "busy work" providing a purely superficial appearance that the Department is assuring that a laboratory is maintaining operational accuracy.

For these reasons, it is also unjustified for the Department to require a new IDC whenever equipment is relocated. IDCs are expensive in time and materials. They primarily test procedures, which will not have changed with the movement of equipment. Concerns that testing machines may have been affected by the jostling of being moved between locations or by their position in the laboratory relative to other machines and HVAC can be addressed with much simpler and less costly confirmatory analyses.

6. Other Comments

7.34.4.7(F), definition of Applicant. This definition is only needed and used with respect to patients and caregivers. There is no need to include producer applicants in the definition, and it creates ambiguity.

7.34.4.7(R) and (X), definitions of diversion and inversion are over-broad, and make the definitions less useful, and potentially subject to void for vagueness challenges if any transfer of cannabis that is unlawful; i.e., in violation of any rules, is a diversion/inversion. The Department should narrow these definitions to pertain to transfers from or to persons who are not licensed entities.

7.34.4.7(II). The LECUA requires that the Department issue patient registrations upon a practitioner's certification; it would be unlawful for the medical director to exercise the power provided in this definition.

7.34.4.7(RR). It exceeds statutory authority for the Department to exclude petitions for covered conditions from persons who are not residents.

7.34.4.8(A)(2) and (K). The Department reasonably licenses multiple production facilities under a single license. Concurrent operation of an indoor and an outdoor grow is common in the program, and is desirable for allowing producers to produce medicine to meet patient needs year-round, at the lowest cost. The rules at .8(A)(2) should state "one or more facilities" and not imply a restriction to "a facility" for clearness. In addition, at subpart K, the rules should not restrict production to one facility, nor allow facilities at the Departments arbitrary "discretion." .8(A)(2) should be rewritten to state "A producer shall conduct its operations only at the physical locations approved by the department, which facilities shall be reasonably necessary to supply the cannabis needs of the patients served by the producers, and whose numbers and locations shall not unreasonably burden the department's ability to monitor production activities."

Thank you for your attention to these comments.

Sincerely,

Jason Marks

[EXT] Attn:Andrea Sundberg NM Department of Health Medical Cannabis Program

[redacted]

Thu 1/16/2020 9:04 AM

To: comment, MCP, DOH <MCP.Comment@state.nm.us>;

NOTICE OF PUBLIC HEARING **PUBLIC COMMENTS.**

Hello, My Name, is [redacted] and I am a member of the New Mexico Medical Cannabis Program and Patient Advocate Alliance.

TOP Priority OPEN up “micro business” licenses immediately in preparation to compensate for Rec use is implemented. Allow small family farms and entrepreneurs to enter the market to be able to sell to LNPPs for Medical/Rec use, allow Micros to sell directly to medical patients who have specific needs.

Allow 3rd party business to test, process and package for a patients to have their medication administered as specifically needed: e.g. Tinctures, FECO, Topicals, extractions as well and edible manufacturing carts ECT.....
Include program funded grows for veterans and a system set up for low cost meds for those in poverty on fixed income and no ability to afford adequate medication.

Consumption areas for qualified patients, Should NOT be Limited to LNPP sites that are operated by any business to participate by approval of an application to be anywhere and everywhere. Near military bases, reservations, and near borderlines. PATIENTS NEED THIS!
Example: Tattoo shops to offer a dab for pain control, Huka Lounges, Hotels, Bud and Breakfast, cafes or coffee shops and restaurants with infused cuisine menu.

"Cannabis testing to include also mold, heavy metals and to have a Member of the DOH to cut the samples from bottom, middle and tops.

[EXT] Written Public Comment Regarding the MCP Rule Amendments

[redacted]

Thu 1/16/2020 9:10 AM

To: comment, MCP, DOH <MCP.Comment@state.nm.us>;

Hello and Good Morning,

I am writing this comment as a patient, advocate, and cannabis educator to express my concern for the accessibility, affordability, and quality and cost of medicine available to patients on the NMMCP through LNPPs. As someone with first hand experience with my own medical and health conditions as well as getting to know the stories of hundreds of patients I've met and helped I believe our program would greatly benefit from the opening of licenses/the ability for micro licensing (for many reasons but first and foremost for accessibility for patients in rural areas), a more honest and unbiased testing solution/facility/entity, and how to overall improve the quality and cost of the medicine available to the patient base we already have before jumping headlong into a rushed recreational bill. Please consider how many patients across our beautiful and diverse state use this medicine daily and completely depend on its amazing benefits and how these rule changes literally affect the lives of thousands of chronically ill New Mexicans. Thank you for your time and consideration. Have a wonderful day.

[redacted]

[EXT] Re: Questions // Comments

[redacted]

Thu 1/16/2020 10:10 AM

To: comment, MCP, DOH <MCP.Comment@state.nm.us>;

PS. The 100 square foot suggestion was intended for outdoor growers. Maybe something closer to 36 square feet for indoor growers.

On Thu, Jan 16, 2020 at 9:32 AM [redacted] wrote:

> Hello,
>
> As a medical patient, I have concerns with the current state of the Personal Production License system.
>
> To set an arbitrary limit of 4 plants in flower highly limits the ability of individuals to find and maintain a library of varieties that work for their ailments.
>
> One could grow more cannabis with 4 large plants, than they could with 25 small ones - depending on lighting, canopy area, soil volume, etc.
>
> I understand where the idea came from, to limit the growth of cannabis in unlicensed facilities, to try and mitigate spill over into the black-market.
>
> My suggestion would be to assign a maximum flowering canopy area, say 100 square feet in flower. To allow those interested in growing many small plants for selection the opportunity to do so, while also curtailing those who may try to abuse the 4 plant system by growing significantly larger plants than others.
>
> Sincerely,
> [redacted]

[EXT] Tyler Heeman January Comments

[redacted]

Thu 1/16/2020 9:42 AM

To: comment, MCP, DOH <MCP.Comment@state.nm.us>;

1 attachment

MedicalAdvisoryBoard1.16.19.docx;

TO: Medical Cannabis Advisory Board

Hello,

My Name is [redacted] I have been a Cannabis patient in the state of New Mexico since 2014. Since then I have witnessed many great changes in the program, and we are thankful for those changes. However, there are some glaringly obvious problems that seem to be ignored.

1. The most important issue to me is seeing the state of the LNPP licenses and how constricted they are to produce. I work with some of these LNPPs and its obvious to me that they are not committed or have found ways to produce minimum quality and quantity and coast because they have a steady supply of patients who RELY on them for medicine despite the quality and quantity available. This is extremely unfair to the patients who rely on HIGH quality cannabis in order to medicate. The 34 or so active LNPP licenses are a small pool of growers who do not represent the full market. By capping the licenses, the state has essentially protected many of these LNPPs from worrying about competition or keeping their cannabis to the status quo of the industry. Simply put our LNPPs are WAY behind when it comes to cultivation and there is no opportunity for the REAL growers to bring their medicine to the patients. It takes GREAT dedication, experience, and knowledge to grow quality cannabis and be able to support the demand of the patients. And the ones who need to be growing are stuck at the starting gates because of the state of the LNPPs
2. Increased testing requirements are only going to stifle and slow the growth of the already lagging LNPPs. As you make it harder and harder for the very few LNPPs to produce proper amounts of medicine, it only pushes the patients back to the streets where they are receiving MUCH higher quality medicine and MUCH more fair prices.
3. Why do we have recertification requirements for people who have their card for Chronic diseases? Why is a patient who KNOWS they are going to need cannabis for an extended period, forced to spend 40-100$ a year to recertify? I would like to see a provision made for chronic illness card holders.
4. I would love to see a report on the negative affects of our cannabis program. As a patient I get the feeling that this program is being run with a minimalist mentality. We started the program FEARING what it could become and because of that we put HEAVY limitations on production and licensing. To me the Act has done nothing but improved the lives of patients and citizens alike and we need to stop going forward with the smallest program possible mentality.

[redacted]

[EXT] X-Ray Comments on Proposed Rule.1

Greg Miller <doctor.arsenic@gmail.com> on behalf of xraypharms@gmail.com

Thu 1/16/2020 9:44 AM

To: comment, MCP, DOH <MCP.Comment@state.nm.us>;

Hi,

I will be submitting additional comments today until the close of the hearing.

Best regards,

Greg

X-Ray Pharms Comments on Public Hearing NMAC-201910-MCP-Public-Hearing-2-7.34.4-Comparison

The Analytical Requirement Rule Development is Non-Transparent and Fatally Flawed

The majority of X-Ray Pharms comments relate to technical aspects of the proposed rule pertaining to manufacturers. This comment is on the outcome of the current process as it relates to analytical requirements. We see a general problem in trying to incorporate technical specifications, guidance, and detailed quality assurance protocols directly into the rule.

We find the efforts of DOH to raise the bar on quality and patient confidence laudable. The lack of a qualified technical working group with experience in:

- cannabis chemistry;
- analytical chemistry;
- manufacturing and analytical quality assurance and control;
- human toxicology; and

other health and science disciplines, impedes the effort to create a workable, technically accurate rule that meets the public interest.

We have watched and participated in the rulemaking whenever allowed or invited and are troubled by the non-transparent process by which analytical requirements are being set. There have been sweeping changes proposed, in several incarnations, with no way for the public or regulated entities to hear the logic behind any of the changes made.

A single example, Table 1 from the proposed rule, demonstrates that the outcome of the current proposed DOH MCP rule revision is fatally flawed. We suggest that DOH and MCP withdraw the proposed rule as related to analytical requirements in its entirety and engage in a process similar to that used by the State of Oregon to discover and publish the rationale for their testing requirements. Anything else is ad hoc and not transparent to the public.

Table 1 of the proposed rule lists all of the cannabis products (10) that require microbial testing. X-Ray Pharms products are not included in Table 1, not a single one. Many of the products suggested (water based) are not made because THC and CBD are not water soluble. Nobody is selling cannabis tea bags in New Mexico. Given that analytical requirements flow down from Table 1 products, we don't believe another run to the reference documents and re-edit will fix the rule.

The analytical portions of the rule have not been created in a transparent or scientifically defensible manner. The revisions to the analytical program should not be re-proposed until a technical guidance document has been developed by an approved, public, working group. We suggest that the rule reference performance standards only, and address implementation in a living, enforceable, technical guidance document.

[EXT] Input concerns

[redacted]

Thu 1/16/2020 9:45 AM

To: comment, MCP, DOH <MCP.Comment@state.nm.us>;

I [redacted] I'm a patient of the state of New Mexico. The fact is that this is the medicine I resort to due to different facts. 1. I do not support pharmaceuticals and their greed of no care what so ever towards their patients and addictions. 2. Side effects on pharmaceuticals can be more negative than any amount of marijuana I consume and is proven by science. That is until i stopped black market purchases because of so many "foreign" substances found in cannabis now a days, so I resort to non profit licensed distributors which have definitely STOLE every single one of my pennies. No one should ever pay for medicine that is not correctly tested and therefore SHOULD NEVER BE CONSUMED! After consuming for years I no longer want to invest my hard working money in the greed profits of industries that pledge the care of patients. PPL is what I opt for because I know what is going into my product but I also do want other people to experience quality medication we deserve without having the need to resort into black market. Price for production licensee is OUTRAGEOUS. I ask that a micro license option is available so that many non profit producers can get their hands ON REAL PRODUCT and supply patients with a HEALTHY medication along with testing of course. This state can not become recreational if there is not enough producers and if the price to become one is outrageous how will we ever succeed? I ASK NO MORE GREED.

[EXT] Medical Cannabis Hearing Commentary

[redacted]

Thu 1/16/2020 10:27 AM

To: comment, MCP, DOH <MCP.Comment@state.nm.us>; [redacted]

Hello,

my name is [redacted]. I've had my medical card since the start of the program and testified to pass the Lynn and Erin Compassion Act in 2007. I was born and raised in [redacted]. I graduated High School from [redacted] and college from The University of New Mexico in Albuquerque. I lived in the state of Oregon from 2012-2018 and was a patient in that state as well and experienced the shift from Medical Cannabis to Recreational. I worked at a dispensary and saw mediocre flower, I've also seen amazing flower. My point is I've been around a lot in this realm. I've grown my own, I've gone to the black market to get my medicine I've dealt with the dispensaries to get my medicine. I'm [redacted] and have grown up around Cannabis. So here is what I think from what I've seen.

The proposed rule revision 7.34.4 NMAC concerning reciprocity. I believe you should make it as open and accepting and as easy for patients to get medicine or travel on their way through a different state as possible. I can tell you driving back to to visit my family in New Mexico from Oregon it was stressful to determine travel route. I tried to determine best path for me to carry my medicine legally as California and AZ had reciprocity, Idaho and Utah were very conservative on the subject and Nevada during some of those years wasn't the best either. Also once I got to New Mexico they weren't reciprocating so I was always nervous if I stayed with my parents for a couple weeks over Christmas what if I got checked and the police didn't care if I had my card or not. So just let all the medical states be legit here too.

The proposed rule revisions also include provisions for the establishment and operation of cannabis consumption areas. I have not experienced this type of scenario, these areas didn't not exist in Oregon and I cannot comment on whether this would be good for patients and a help to them or not. But if I was a deciding on these proposals I would look at every single thing in the light of if it helps the patients or not, can this be corrupted by big business, what are other states doing, and is it working elsewhere? Before you approved anything. As for Cannabis testing this should be the utmost priority. There is no influx of amazing top shelf high testing medicine available in a variety of strains down here probably at any of the dispensaries. With that being said, the best cannabis comes from personal growers and producers and the black market. The dispensary can fail at growing and still somehow sell their products to people and make a large profit. A black market grower cannont fail or no one is gonna buy his pardon my language shit! Also patients who are able bodied enough to grow can have some of the most amazing medicine because it is a craft. They are connoisseur small time growers and that is the best type of flower plain and simple. Nobody wants mass produced commercialized flower from a huge grow op. So whatever you do, please please please allow patients to be allowed to sell their overflow if it is tested top notch back to the dispensaries at fair or above market value or maybe in some cases credit. And in a way I hate to say it but if there was a don't ask don't tell policy where someone could bring say a man takes 1/4 lb or maybe up to a lb of top shelf cannabis testing at 28-30% to the dispensary to be purchased. He gets paid fair, and the dispensary gets paid just as much or more (probably more) than him. I mean the patients would be the ones benefiting from the quality medicine and even if that guy is black market and considered a "bad man", well he's getting the chronic from somewhere and we don't care because it's better medicine than we've ever been provided before.

In regards to Cannabis packaging. I'd like to know real testing and dates of things and somehow get rid of the plastic. The plastic joint holders and the little rx containers very quickly became the most littered item in Oregon after cigarette butts. Literally hiking out in the forests and plastic weed waste was everywhere! Disgraceful! Please don't let this happen here and make dispensaries re-use or use kitchen parchment or compostable materials.

Other comments suggestions: Maybe police the cars coming down from Colorado if worried about black market. Don't allow out of state producers or big businesses to set up in NM. Allow small time patient growers as much freedom as possible to help alleviate the lack of quality medicine, implement a patient co-op so we can buy and sell from each other.

Thank you for your time,

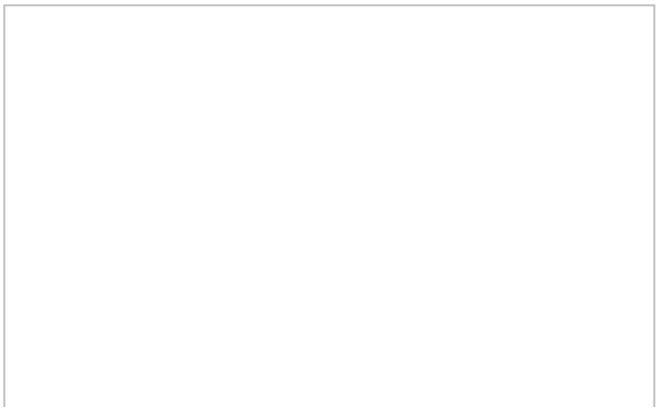
[redacted]

[EXT] January 16th 2019 Medical Cannabis Program Proposed Rules Hearing Public Comment

[redacted]

Thu 1/16/2020 10:27 AM

To: comment, MCP, DOH <MCP.Comment@state.nm.us>;



Safe Access New Mexico

[redacted]

Wednesday, January 15th 2019

Andrea Sundberg
NM Department of Health
Medical Cannabis Program
P.O. Box 26110
Santa Fe, NM 87502-6110

MCP.comment@state.nm.us

Safe Access New Mexico would like to thank the Department of Health for the opportunity to provide public comment for the January 16th 2019 Medical Cannabis Program Proposed Rules Hearing.

Introduction:
Today the New Mexico Medical Cannabis Program has over 80,257 registered participants with almost 300 of those participants being pediatric medical cannabis patients. The medical cannabis program now has 28 qualifying health conditions, six new health conditions were added in 2019. Of the new health conditions added to the medical cannabis program in 2019, five (5) of those new ones were Petitioned by Safe Access New Mexico, approved by medical cannabis advisory board, and added into the program by the Dept. of Health.

The Dept. of Health has issued 35 licenses for the production of medical cannabis but currently there are only 34 active licenses or LNPPs and those 34 LNPP's operate over 85 dispensaries across New Mexico. One producer had their license taken away by the Dept. of Health and nothing has been done to license a new program producer.
These 34 medical cannabis producers are now growing 39,400 cannabis plants in a 3-5 month cycle which only provides ½ of a medical cannabis plant worth of medicine per patient.

The state has a serious issue with Adequate Supply for the Medical Cannabis Program.

Public Comment For:
NMAC 7.34.4 — Medical cannabis licensing requirements for producers, couriers, manufacturers and laboratories. 7.34.4.10 TESTING OF USABLE CANNABIS:
Section (1) sampling and segregation / Table 7. Minimum Test Sample Size
(Page 19 -20: https://nmhealth.org/publication/view/rules/5404/)

The Minimum Amount Required for Testing (grams) appears to have serious two typos stating 10.0 gram needed for these tests when it should be 1.0 grams needed. As 10.0 grams would be beyond excessive and not necessary to conduct those tests.

Targeted Parameter	Sample Matrix	Analysis Platforms (Instrumentation Used by Lab)	Minimum Amount Required for Testing (grams)	
Absence of Salmonella spp. & E. coli	dried usable cannabis, cannabis derived product	Culture, biochemical, antibody, or nucleic acid based assays shall be validated microbiological methodology such as FDA, USP, AOAC, or equivalent.	10.0	
Total Aerobic Microbial Count Total Combined Yeast & Mold Count Bile-tolerant Gram negative Bacteria Total Coliforms Count	dried usable cannabis, concentrate, or cannabis - derived products	Direct culture, indirect culture, or non-culture based. Must be validated microbiological methodology such as FDA, USP, AOAC, or equivalent.	10.0	

The following cannabis industry experts and leading labs can provide the state the correct guidance for correcting the quantities needed to conduct these tests:

Americans For Safe Access Regulator's Program Guide (May 2019)
1. Cannabis Cultivation and Processing Operations;
2. Cannabis Manufacturing, Packaging, Labeling, and Holding Operations;
3. Cannabis Laboratory Operations; and
4. Cannabis Dispensary Operations (see appendix).
https://american-safe-access.s3.amazonaws.com/Regulators_Program_Guide_2019.pdf

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CannaSafe
CannaSafe has established itself as one of the most trusted names in safe cannabis. Being the first accredited Cannabis lab in the world has its advantages.
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https://www.medicinalgenomics.com/microbial-test/
https://www.medicinalgenomics.com/enterobacteriaceae/

Steep Hill
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Email: info@steephill.com
https://www.steephill.com/science

Dr. Reggie Gaudino presentation about to NM Lawmakers.
https://www.nmlegis.gov/handouts/LHHS%20101617%20Item%209%20Dr.%20Reggie%20Gaudino%20Testimony%20with%20NM%20Samples%2010_17_17.pdf

Steep Hill's sample mass requirements for R&D Testing:
- Every individual test requires---
1 gram for flowers
1 gram concentrates
2 grams for cartridges (Four 0.5g carts or two 1g carts)
4 ml for oils, liquids and butters
1 unit for edibles (must be over two grams total weight)
1 unit for topicals
Below you will find the Cannabis testing regulations for California:
https://bcc.ca.gov/law_regs/cannabis_order_of_adoption.pdf
On page 98-99 it explains the minimum amount of sample we need for compliance testing.

American Herbal Products Association (AHPA)
Address: 8630 Fenton Street, Suite 918, Silver Spring, MD 20910
Phone: 301.588.1171
Email: ahpa@ahpa.org

American Herbal Products Association (AHPA) Cannabis Committee
http://www.ahpa.org/AboutUs/Committees/CannabisCommittee.aspx

This document includes the following Recommendations for Regulators:
• Laboratory Operations
http://www.ahpa.org/Portals/0/PDFs/Committee/CC/Cannabis_Laboratory_Recommendations_Regulators.pdf?ver=2016-02-23-150853-300

AgriScience Labs
o: 303-292-3800
a: 2120 S Birch St Denver, CO 80222
You can find our regulations at https://www.sos.state.co.us/CCR/GenerateRulePdf.do?ruleVersionId=8439&fileName=1%20CCR%20212-3 . It begins on page 175.

Here are the limits we need for testing: https://hubs.ly/H0mzflw0

http://agrisciencelabs.com/

In Conclusion:
Unfortunately 2019 has been a rough year for the state medical cannabis program participants. Please keep the focus on cannabis policy in 2020 on the medical cannabis program and protecting the program like Governor Lujan Grisham has promised. There has also not been any state legislator that has

informed the patient community of any legislation to address any of these problems in the medical cannabis program, once more this past year the patients voice has been ignored.

The state has three medical cannabis laws, all three have multiple violations being allowed to occur in 2019 and now; and all of these violations are being ignored by the State of New Mexico.

1.Medical Cannabis in School Law was improperly enacted by the Public Education Department (SB-204) and the law is not being followed. Kids are still being discriminated against by the schools.

- ‘Dad pleads for medical cannabis’ | Friday, November 22nd, 2019 | ABQ Journal | https://www.abqjournal.com/1394537/dad-pleads-for-medical-cannabis.html

- ‘Gov. candidates disagree on medical cannabis at school’ | ABQ Journal | https://www.abqjournal.com/1240091/gov-candidates-disagree-on-parcc-other-education-issues.html

- “The PED, APS, Rio Rancho, and schools across the state are all disciplining students and their families, as they are denying eligibility to attend school by not allowing for a reasonable accommodation necessary for the student to attend school.”

  ‘Fix medical pot before going recreational’ | Jan. 2020 | ABQ Journal | https://www.abqjournal.com/1409174/fix-medical-pot-before-going-recreational.html

2. "Adequate Supply" and "Purpose of the act" in the original The Lynn And Erin Compassionate Use Act are not being followed.
The fact of the matter with the New Mexico medical cannabis program plant count being decreased from 2500 cannabis plants to 1750 cannabis plants in 2019, that was done as a means of price control, period. It had nothing to do with “Adequate Supply”, as the medical cannabis program law demands.

The Program has over 80,000 participants and the program grows less than 40,000 cannabis plants that clearly is not “adequate supply”.

A research assessment of physical and pharmacokinetic relationships in cannabis production and consumption in New Mexico hasn't ever been done in relation to Equivalency in Portion and Dosage for the medical cannabis program for establishing a plant count to provide “Adequate Supply”.
Here is one Colorado has done:
https://www.colorado.gov/pacific/sites/default/files/MED%20Equivalency_Final%2008102015.pdf

3. The Dept. of Health, MCP Office, and the MCAB did not fulfill their duties and responsibilities for the LECUA law (2007) in 2019.
The advisory board shall convene at least twice per year. Nor were the Public hearing responsibilities followed or fulfilled for the MCAB hearing as outlined in law and Rules & Regs. The chairperson did not

conduct a fair and impartial proceeding, did not assure that the facts were fully elicited and now the hearing completion is delayed.

- 'Cannabis advisory board meeting unable to address qualifying conditions due to lack of quorum' By Andy Lyman | NM Political Report | December 10, 2019 | https://nmpoliticalreport.com/2019/12/10/cannabis-advisory-board-meeting-unable-to-address-qualifying-conditions-due-to-lack-of-quorum/

Governor Lujan Grisham has said that she wants the medical cannabis program protected before recreational cannabis legalization. And that is exactly where the focus should be - on the medical cannabis program.

More concerning is the fact that the Governor's Legalization Work Group Recommendations Open The Door To Federal Interference. The US Senate sent President Trump the Fiscal Year 2020 spending legislation that continues a budget rider protecting state medical cannabis laws from federal interference. Congressional negotiators cut House-passed measures protecting all state cannabis laws from federal interference and cut the measure allowing cannabis banking from 2020 spending legislation. The bill also continues a budget rider blocking Washington, D.C. from spending its own money to regulate recreational cannabis sales.

Medical cannabis patients in New Mexico and the state of New Mexico may find themselves without those federal protections as the Governor's Legalization Work Group recommends adopting a totally new model for a joint medical-adult use program in New Mexico.

Those federal CJS Medical Cannabis budget rider protections do not apply to a joint medical-adult use program laws. This would also have a devastating impact on the new medical cannabis in schools law, if the state is not protected from Federal interference.

- Read more about this at: 'Governor's Legalization Group Recommendations Open The Door To Federal Interference' | Cannabis News Journal | http://www.cannabisnewsjournal.co/2019/12/governors-legalization-group.html

This is exactly why the medical cannabis program laws need to be separate from any proposed legalization legislation in New Mexico for 2020.

Using the state's medical cannabis program to create a recreational cannabis program will result in great harm coming to the state's medical cannabis program, Americans For Safe Access policy expertise advises that any system of regulation should not be built on the backs of current medical cannabis laws.

Issues such as access, police harassment, and the price and quality of medicine will still be relevant to the patient community despite the adoption of a policy of legalization for recreational use. The federal refusal to recognize the medical efficacy of cannabis causes more harm and difficulty for patients than any failure by local or state governments to adopt policies of legalization of cannabis for recreational use. Any system of regulation should not be built on the backs of current medical cannabis laws.

The legalization of cannabis for recreational use is a separate issue from safe and legal access to cannabis for therapeutic use. Americans For Safe Access cautions policy makers against letting the debate surrounding the legalization of cannabis for recreational use obscure the science and policy regarding the medical use of cannabis.

To learn more about Safe Access New Mexico please view our Community Report here:
'Safe Access New Mexico 2019 Community Advocacy Report' | Cannabis News Journal |
http://www.cannabisnewsjournal.co/2019/11/safe-access-new-mexico-2019-community.html

'Policy Letter to Governor Michelle Lujan Grisham Formally Requesting Cannabis Legislation for 2020' | Cannabis News Journal | Sent Oct. 2019 |
http://www.cannabisnewsjournal.co/2019/10/policy-letter-to-governor-michelle.html

Please defer recreational cannabis to a special session in the fall of 2020, if the proponents are right about the financial gains for the state then recreational cannabis sales will easily cover the state's cost at doing the special session for legalization.

Please keep the focus on cannabis policy in 2020 on the medical cannabis program and protecting the program like Governor Lujan Grisham has promised.

Most Respectfully Yours,

[redacted]

Sources:

'Congress sends spending deal to Trump, ending shutdown threat' | 12/19/2019 | Politico |
https://www.politico.com/news/2019/12/19/senate-moves-to-avoid-shutdown-with-passage-of-spending-deal-087898

'House-Passed Marijuana Amendments Stripped From Congressional Spending Bills' | December 16, 2019 | https://www.marijuanamoment.net/house-passed-marijuana-amendments-stripped-from-congressional-spending-bills/

'The House of Representatives approved Fiscal Year 2020 spending legislation that continues a rider protecting state medical cannabis laws from federal interference but also blocks Washington, D.C. from spending its own money to legalize marijuana sales.' |
https://www.politico.com/news/2019/12/17/house-passes-massive-deal-to-fund-government-and-avoid-shutdown-086514

"The PED, APS, Rio Rancho, and schools across the state are all disciplining students and their families, as they are denying eligibility to attend school by not allowing for a reasonable accommodation necessary for the student to attend school."
'Fix medical pot before going recreational' | Jan. 2020 | ABQ Journal |
https://www.abqjournal.com/1409174/fix-medical-pot-before-going-recreational.html

"We do enabling legislation and it's up to the districts to do the right thing, and in this instance they've done the opposite of the right thing," he said. "They've abused their authority and discretion to deny kids an education, period."
'Legislators could strip school districts of discretion over medical cannabis in schools' | NM Political Report | https://nmpoliticalreport.com/2019/10/28/legislators-could-strip-school-districts-of-discretion-over-medical-cannabis-in-schools/

'Policy Letter Seeks Executive Order By New Mexico's Governor For Medical Cannabis in School Law' | Cannabis New Journal | Sent Oct. 2019 | http://www.cannabisnewsjournal.co/2019/10/policy-letter-seeks-executive-order-by.html

'Legislators pushing for revisions to medical marijuana in school law' | KRQE 13 | https://www.krqe.com/news/health-news/legislators-pushing-for-revisions-to-medical-marijuana-in-school-law/

'APS medical pot directive: Parents must dose kids at school' Sept. 2019 | ABQ Journal | https://www.abqjournal.com/1364958/aps-medical-pot-directive-parents-must-dose-their-kids.html

'Who should administer cannabis in schools?' | Rio Rancho Observer | https://www.abqjournal.com/1372600/who-should-administer-cannabis-in-schools.html

"I'm disappointed and dismayed at how this was implemented," Sen. Antoinette Sedillo Lopez, D-Albuquerque, said during a hearing at the Capitol."
'Legislators may revisit law on medical cannabis at school' Oct. 2019 | ABQ Journal | https://www.abqjournal.com/1382766/legislators-may-revisit-school-cannabis-law.html

'No medical cannabis at schools despite new state law' | KOAT 7 | https://www.koat.com/article/no-medical-cannabis-at-schools-despite-new-state-law/28791724

'Medical marijuana advocates concerned over recreational cannabis proposals' | KOB 4 News | https://www.kob.com/albuquerque-news/medical-marijuana-advocates-concerned-over-recreational-cannabis-proposals/5530502/

"But the parts of the law that are supposed to protect patients from losing their jobs solely for being a patient in the program may also be hindering the nearly 79,000 cannabis patients in New Mexico from getting a job with the state. That's because the law also protects employers by giving them enough autonomy to fire or not hire a cannabis patient for safety concerns or if the employer could lose federal funding for hiring a cannabis user."
'State job opportunities limited for medical cannabis patients' Dec. 2019 | NM Political Report | https://nmpoliticalreport.com/2019/12/06/state-job-opportunities-limited-for-medical-cannabis-patients/

[redacted] with the New Mexico Medical Cannabis Patients Advocate Alliance said the state should focus on making sure patients in rural areas have access to cannabis before branching out to recreational legalization. [redacted] lives in Ruidoso and said many dispensaries in his area have a hard time keeping up with demand."
'Mixed responses to suggestions from marijuana legalization work group' | NM Political Report | https://nmpoliticalreport.com/2019/10/17/mixed-responses-to-suggestions-from-legalization-work-group/

"If lawmakers in New Mexico are going to take on the failed war on drugs, then please finish what you started with medical cannabis. Please focus on how the Medical Cannabis in Schools law passed this year is being ignored by the Public Education Department and all the schools that are keeping kids who are medical cannabis patients from being able to attend their school."
'Work group's plan will devastate medical pot' | ABQ Journal | https://www.abqjournal.com/1383936/work-groups-plan-will-devastate-medical-pot.html?fbclid=IwAR0aBEuhgvrS4FKSeEPROpHUaMOCJNmIpYBXv1_d8mJtXcvME8zQy7UpQXQ

'NM drinking water is the wrong source to irrigate pot farms' | Albuquerque Journal | Tuesday, January 14th, 2020 at 12:02am | https://www.abqjournal.com/1409520/nm-drinking-water.html

"New Mexico as it stands just does not have the logistics for recreation, said Chad Lozano, secretary of the New Mexico Medical Cannabis Patients Advocate Alliance."
'Medical cannabis experts caution against New Mexico's push to legalize recreationally' | ABC 7 KVIA | https://kvia.com/news/2019/12/23/medical-cannabis-experts-caution-against-new-mexicos-push-to-legalize-recreationally/

'Advocates petition to allow medical cannabis to be administered to animals' | Dec. 2019 | KOB 4 | https://www.kob.com/albuquerque-news/advocates-petition-to-allow-medical-cannabis-to-be-administered-to-animals/5574622/?cat=500

"Board stalls on medical marijuana policy"
'RRPS wrestling with bus deficits, medical pot' | Nov. 2019 | ABQ Journal | https://www.abqjournal.com/1387944/rrps-wrestling-with-bus-deficits-medical-pot.html

'Medical marijuana users struggle to keep up with costs' | Nov. 2019 | ABQ Journal | https://www.abqjournal.com/1386640/medical-marijuana-users-struggle-to-keep-up-with-costs.html
The school district is now breaking the law by failing to meet the "reasonable accommodation" aspect of the law by forcing parents to come to school when school personnel need to be doing their job and handling the student's medication needs.
'Social Equity and New Mexico's Medical Cannabis in Schools Law' | Cannabis News Journal | http://www.cannabisnewsjournal.co/2019/09/social-equity-and-new-mexicos-medical.html

'Aztec school board approves medical cannabis policy for students' | FDT | https://www.daily-times.com/story/news/2019/12/20/medical-marijuana-policy-approved-for-aztec-schools-students/2690991001/

"A person who is serving a period of probation or parole or who is in the custody or under the supervision of the state or a local government pending trial as part of a community supervision program shall not be penalized for conduct allowed under the Lynn and Erin Compassionate Use Act." NM Stat § 26-2B-10"
'Medical cannabis patient asks judge to allow cannabis on house arrest' By Andy Lyman | NM Political Report | Jan. 2020 | https://nmpoliticalreport.com/2020/01/09/medical-cannabis-patient-asks-judge-to-allow-cannabis-on-house-arrest/

"Fifty-five percent of our producers are having trouble meeting the demand for those products already and if over half of the people in the program can't produce that quickly enough, if we roll into a recreational law then it would be a great concern for me and a lot of the other patients,"
'Medical marijuana advocates concerned over recreational cannabis proposals' | KOB 4 News | https://www.kob.com/albuquerque-news/medical-marijuana-advocates-concerned-over-recreational-cannabis-proposals/5530502/?cat=500

"Under the new fee schedule, it will be impossible for all producers to meet the 1,750 maximum and cultivate an adequate supply of medicine for patients,"
'Cannabis producer says state is pricing out smaller producers, limiting access to medicine' | NM Political Report | https://nmpoliticalreport.com/2019/10/21/cannabis-producer-says-state-is-pricing-out-smaller-producers-limiting-access-to-medicine/
"the fact that Lujan Grisham's group recommends the state subsidize medical marijuana through the recreational market — if one is approved — and supply the medical market first, doesn't cut it.
The $180,000 in annual fees for growing the maximum amount is far too prohibitive for most growers, he said, and until medical marijuana is covered through Medicaid and private health insurance, patients will always be at risk of a supply shortage. But he sees the cap on plants per producer as the biggest problem."
'Medical pot producer sees hole in New Mexico legalization report' | Santa Fe New Mexican | https://www.santafenewmexican.com/news/local_news/medical-pot-producer-sees-hole-in-new-mexico-legalization-report/article_e7e0e4d0-2ccf-5dbc-8127-c4b30fd134e8.html

'Students who depend on medical cannabis one step closer to getting it at school' | Aug. 2019 | KOAT 7 | https://www.koat.com/article/school-districts-to-decide-how-medical-cannabis-will-be-administered-to-students/28836362

'Homework for PED: Make rules match law on medical pot' | ABQ Journal | https://www.abqjournal.com/1350592/homework-for-ped-make-rules-match-law-on-medical-pot.html

'New Mexico is now the 8th Medical Cannabis State to allow Safe Access to Medical Cannabis at Schools' | April 11, 2019 | Americans For Safe Access | https://www.safeaccessnow.org/new_mexico_is_now_the_8th_medical_cannabis_state_to_allow_safe_access_to_medical_cannabis_at_schools

"Legislators listened at a public hearing as University of New Mexico economics professor Sarah Stith cautioned against legalization measures that might make retail prices uncompetitive with Colorado's recreational market, through restrictions on supplies or excessive taxation."
'Some Democrats, Including Papen, Not Yet Endorsing Marijuana Legalization' | KRWG
https://www.krwg.org/post/some-democrats-including-papen-not-yet-endorsing-marijuana-legalization
'Dad pleads for medical cannabis' | Friday, November 22nd, 2019 | ABQ Journal |
https://www.abqjournal.com/1394537/dad-pleads-for-medical-cannabis.html

'Gov. candidates disagree on medical cannabis at school' | ABQ Journal |
https://www.abqjournal.com/1240091/gov-candidates-disagree-on-parcc-other-education-issues.html

'Cannabis advisory board meeting unable to address qualifying conditions due to lack of quorum' By Andy Lyman | NM Political Report | December 10, 2019 |
https://nmpoliticalreport.com/2019/12/10/cannabis-advisory-board-meeting-unable-to-address-qualifying-conditions-due-to-lack-of-quorum/

'So Tired of Still Fighting for Medical Cannabis Rights' | National Pain Report | 07.28.2019 |
http://nationalpainreport.com/so-tired-of-still-fighting-for-medical-cannabis-rights-8840612.html

'Governor's Legalization Group Recommendations Open The Door To Federal Interference' | Cannabis News Journal | http://www.cannabisnewsjournal.co/2019/12/governors-legalization-group.html

"On a Sunday afternoon over Labor Day weekend, a masked man, armed with a gun, burst through the doors of an Albuquerque medical cannabis dispensary. About two minutes later, he walked back out the door, with an estimated $5,000 worth of cannabis products. In that time, the man hopped over a glass display case and corralled employees and at least one patient into one spot while he emptied a large jar of cannabis—and seconds later cannabis concentrates from the display case—into a bag. After he left, the man got into a car waiting in the back and sped off. All of it was caught on security cameras."
'NM leaves med. cannabis security specifics up to producers' Nov. 2019 | NM Political Report |
https://nmpoliticalreport.com/2019/11/18/nm-leaves-med-cannabis-security-specifics-up-to-producers/

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Safe Access New Mexico
[redacted]

[redacted]

[redacted]

Americans For Safe Access - Member
American Cannabis Nurses Association - Member
[redacted]

"The American Medical Association has no objection to any reasonable regulation of the medicinal use of cannabis and its preparations and derivatives. It does pretest, however, against being called upon to pay a special tax, to use special order forms in order to procure the drug, to keep special records concerning its professional use and to make special returns to the Treasury Department officials, as a condition precedent to the use of cannabis in the practice of medicine."
~Wm. C. Woodward, Legislative Counsel - 11:37 AM Monday, July 12, 1937

[EXT] Proposed Rules and Regulations 1/16/20

[redacted]

Thu 1/16/2020 10:31 AM

To:comment, MCP, DOH <MCP.Comment@state.nm.us>;

Cc:DZurlo@state.nm.us <DZurlo@state.nm.us>;

Dominick Zurlo,

Thank you for allowing this second hearing on the proposed rules and regulations.

1. Testing has always been a priority for me as a patient of the program and an advocate for the program. Yes we do have limited testing and testing is now mandatory. We must add back into the new rules and regulations, pesticide and heavy metal testing. The old saying goes, "no one ever died from smoking cannabis." I would argue pesticides can build up in the tissues an organs of patients. It can take years for the toxic poisons to build up in a patients' body. A toxicology report upon death of a patient might give a better example of damage done.

The LNPP's and the private labs will say testing for heavy metals and pesticides will be too costly. They will be forced to pass the cost onto the already overburden patient. The necessary and long over due issue of pesticide and heavy metals must go in to the Medical Cannabis rules and regulations now. The cost must not be passed on the sick and dying patients of New Mexico.

I propose the State mandate a testing laboratory. The cost to be shared between the State and the LNPPs.

I also propose a change in the way the State allows samples from LNPPs to submit for their medical samples to the labs. I believe state personal be involved in the collections of medical samples to take to the labs. A patient then could hopefully rely then on exact specimen collected.

2. As a patient I am also concerned by the exorbitant new costs for licenses now for the extractors and infusers of our medical program. Once again, this cost will be passed on to the backs of the sick and poor in our state. Please consider revisiting this exorbitant increase.

3. I am asking that the Medical Cannabis Program Director create a new license and do so immediately. We as patients are asking for the licensing of Craft Growers. A smaller Craft Grower can
work with specific strains of medicine that a patient might need. A Craft Grower will have better quality medicine on the whole than the larger grow of an LNPP. A Craft Grower could sell their medicine to the LNPP for their dispensary. Better quality medicine does not necessarily translate into higher prices for the patient.

Thank you for taking my email testimony.

[redacted]

[EXT] MCP.comment

GM Segura <blayze.genetics@gmail.com>

Thu 1/16/2020 10:36 AM

To: comment, MCP, DOH <MCP.Comment@state.nm.us>;

Issues that MUST be addressed:

1. Licensing: Licensing needs to be opened desperately. The number of LNPPs in this state is too small and increasing plant counts is counterproductive. LNPPs with higher plant counts will simply grow more plants with the same number of employees to assist and supervise in the grows. Having more plants with fewer eyes leads to issues like bud rot, powdery mildew, and pest infestations. The quality of product being produced has plummeted with higher plant counts. You don't just need the ability to grow more medicine, but the ability for new players to come in and revitalize a market that has gone stale and incentivize providers that are satisfied with providing mediocre products.

Probably the single best thing that could happen with licensing is to authorize PPL holders and/or micro-cultivators to either have their products tested to be sold direct to patients, or tested and sold by LNPPs, whether on consignment or by LNPPs purchasing from PPL holders/micro-cultivators. This state has spent far too long with a highly limited number of producers, and they have often demonstrated apathy regarding patient health and quality of medicine.

It was not that long ago I purchased medicine from a prominent LNPP just to return home and find that my product was contaminated with mold. Things like that should not happen, especially at the price point patients are expected to pay. Your LNPPs have no motivation to do better, and that must change.

2. Testing: Testing on products must be comprehensive. Heavy metal contamination, pesticides, mold/mildew, and other microbial testing should occur on all products sold in the State. To best ensure that testing is occurring in a randomized fashion, and to eliminate the potential for selective submission of samples, LNPPs should be randomly audited and samples collected for testing.

3. Cannabis consumption areas: There should not be a limitation on cannabis consumption areas to restrict them to LNPP facilities. Especially with the recent string of robberies at dispensary storefronts, patients do not want to spend excessive amounts of time inside retail locations. While it is clear that the government has an interest in protecting public health, and is well within its rights to ban smoking in public areas, the state does not have an interest in ensuring that licensed consumers are restricted to consuming products in a facility operated by an LNPP. Just as the state continues to allow "private clubs" to allow tobacco consumption on site, the state should follow that model for cannabis.

4. Unit counts: I understand the concept behind unit limits. I also understand that unit limits can be raised on request. However, your average cannabis patient is not going to go through the process of attempting to get permission to possess more units. People who run out of units hit the streets, where they often purchase higher quality medicine for a significantly lower price. The more this state's program diverts legitimate customers to illegitimate sources, the worse the program is going to fare.

Additionally, unit limits are, at best, simply arbitrary. The fact that a patient can request an increase in their unit limit is a clear example of that fact. No two patients will medicate the same. No two patients will feel the exact same benefits from the same amount of medication. While one patient with a standard unit count may be fine, other patients may blow through their count in a month or less. Those people are not requesting permission to purchase more; they are simply finding it in places that don't report the additional purchase. Combine the need to purchase from the black market with the clear superiority of black-market products and this program is literally driving people away.

[EXT] Medical Cannabis Hearing comments

[redacted]

Thu 1/16/2020 10:36 AM

To: comment, MCP, DOH <MCP.Comment@state.nm.us>;

Good Morning,
My names is [redacted] and I am a medical cannabis patient here in the state of New Mexico. I am writing you this with concerns of the rules that are currently in effect in the program. These concerns should be addressed and resolved immediately and accordingly.

1. The landlord clause that is currently in effect puts me as well as others in danger of being blackmailed, robbed, and even extorted. This clause allows the landlord to know if we are growing our own medicine within the household. This opens the door for multitude of things to happen to me and my family all while trying to provide safe, clean, quality medicine for myself. I should be able to produce medicine for myself without having anxiety of someone stealing it all because they know I produce for myself at the residence. This clause needs to be done away with for the safety and well being of all the patients in the program that wish to grow their own medicine. My preference of growing my own medicine should be no different than growing vegetables in my garden. There are no other medications out there that require the user to submit a paper for approval before hand. This clause also opens up the certainty of discrimination against me and my family all because I am apart of the cannabis program. I can personally attest to being denied of housing and discriminated against after informing the renting property of my status in the program. If the government has passed the laws that allow me to use my medicine why does it restrict me to where I can and cannot live all because of a landlords say so. I would like to see New Mexico adopt a similar policy to Colorados, in which a patient in the program is allowed by law to grow and posses up to 6 mature plants per patient without the consent of the landlord.

2. The testing in the state of new Mexico is sub par compared to any other cannabis program, as they dont test for heavy metals or pesticides. These both have a serious potential of not only infecting patients but also making their conditions worse than before. The testing for these should not even be up for debate. Every other commodity is tested for all these above mentioned, why is my medicine treated any different. Test samples can esasly be manipulated by the grower. Randomized test and visits by a qualified state representative or third party should be done. The push for better testing is a must for the health and safety of all patients in the program. LNPP's should be evaluated at retail location, manufacturing and growing locations to ensure all protocols, SOP's and state requirements are being complied with.

3. We need to open up more licensing and/or create a micro license which will allow small craft growers and PPL growers to provide their excess medicine to authorized locations for patients to purchase. While the plant count has gone up the quality has gone down the drain. This forces many patients to return to the black market to get medicine that will actually help with their ailments and not leave them under medicated and broke. Please open up license and help save the program.

4. Consumption sites should not be limited to LNPP's, especially in southern New Mexico where locations are scarce and few and far between. Patients should have the options and availability to choose a location that is neutral and comfortable outside and away from the retail location. It almost forces us to buy medicine there in order to be able to consume at these sites if they are located at retail shops

5. Unit limits need to be removed, all of the patients in the program medicate differently. Some require different types of medication. Limiting our medicine forces a lot of us to go to the black market. Most reach their 3 month limit within the first month. Leaving us with no medication for two months or forces us to go to the streets. As a patient I should be able to walk into a retail location and purchase 8oz of cannabis flower so I may process canna butter for cooking. Also gifting to other patients who may need it. Please remove this limitation and stop supporting theblack market and allowing it to thrive.

Thank you for your time and consideration,
A very concerned medical patient.

[EXT] Re: January 16th 2019 Medical Cannabis Program Proposed Rules Hearing Public Comment

[redacted]

Thu 1/16/2020 10:28 AM

To:comment, MCP, DOH <MCP.Comment@state.nm.us>;

1 attachment

January 16th 2019 Medical Cannabis Program Proposed Rules Hearing.pdf;

Comment in PDF file

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Safe Access New Mexico

[redacted]

[redacted] Safe Access - Member
American Cannabis Nurses Association - Member
Medical Cannabis Patient in New Mexico

"The American Medical Association has no objection to any reasonable regulation of the medicinal use of cannabis and its preparations and derivatives. It does pretest, however, against being called upon to pay a special tax, to use special order forms in order to procure the drug, to keep special records concerning its professional use and to make special returns to the Treasury Department officials, as a condition precedent to the use of cannabis in the practice of medicine."
~Wm. C. Woodward, Legislative Counsel - 11:37 AM Monday, July 12, 1937

On Thu, Jan 16, 2020 at 10:27 AM Jason Barker <safeaccessnewmexico@gmail.com> wrote:

Safe Access New Mexico

[redacted]

[redacted]

Wednesday, January 15th 2019

Andrea Sundberg
NM Department of Health
Medical Cannabis Program
P.O. Box 26110
Santa Fe, NM 87502-6110

MCP.comment@state.nm.us

Safe Access New Mexico would like to thank the Department of Health for the opportunity to provide public comment for the January 16th 2019 Medical Cannabis Program Proposed Rules Hearing.

Introduction:
Today the New Mexico Medical Cannabis Program has over 80,257 registered participants with almost 300 of those participants being pediatric medical cannabis patients. The medical cannabis program now has 28 qualifying health conditions, six new health conditions were added in 2019. Of the new health conditions added to the medical cannabis program in 2019, five (5) of those new ones were Petitioned by Safe Access New Mexico, approved by medical cannabis advisory board, and added into the program by the Dept. of Health.

The Dept. of Health has issued 35 licenses for the production of medical cannabis but currently there are only 34 active licenses or LNPPs and those 34 LNPP's operate over 85 dispensaries across New Mexico. One producer had their license taken away by the Dept. of Health and nothing has been done to license a new program producer.
These 34 medical cannabis producers are now growing 39,400 cannabis plants in a 3-5 month cycle which only provides ½ of a medical cannabis plant worth of medicine per patient.

The state has a serious issue with Adequate Supply for the Medical Cannabis Program.

Public Comment For:
NMAC 7.34.4 — Medical cannabis licensing requirements for producers, couriers, manufacturers and laboratories. 7.34.4.10 TESTING OF USABLE CANNABIS:
Section (1) sampling and segregation / Table 7. Minimum Test Sample Size
(Page 19 -20: https://nmhealth.org/publication/view/rules/5404/)

The Minimum Amount Required for Testing (grams) appears to have serious two typos stating 10.0 gram needed for these tests when it should be 1.0 grams needed. As 10.0 grams would be beyond excessive and not necessary to conduct those tests.

Targeted Parameter	Sample Matrix	Analysis Platforms (Instrumentation Used by Lab)	Minimum Amount Required for Testing (grams)	

Absence of Salmonella spp. & E. coli	dried usable cannabis, cannabis derived product	Culture, biochemical, antibody, or nucleic acid based assays shall be validated microbiological methodology such as FDA, USP, AOAC, or equivalent.	10.0	
Total Aerobic Microbial Count Total Combined Yeast & Mold Count Bile-tolerant Gram negative Bacteria Total Coliforms Count	dried usable cannabis, concentrate, or cannabis - derived products	Direct culture, indirect culture, or non-culture based. Must be validated microbiological methodology such as FDA, USP, AOAC, or equivalent.	10.0	

The following cannabis industry experts and leading labs can provide the state the correct guidance for correcting the quantities needed to conduct these tests:

Americans For Safe Access Regulator's Program Guide (May 2019)

1. Cannabis Cultivation and Processing Operations;
2. Cannabis Manufacturing, Packaging, Labeling, and Holding Operations;
3. Cannabis Laboratory Operations; and
4. Cannabis Dispensary Operations (see appendix).

https://american-safe-access.s3.amazonaws.com/Regulators_Program_Guide_2019.pdf

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CannaSafe
CannaSafe has established itself as one of the most trusted names in safe cannabis. Being the first accredited Cannabis lab in the world has its advantages.
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https://www.medicinalgenomics.com/microbial-test/
https://www.medicinalgenomics.com/enterobacteriaceae/

Steep Hill
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General Inquiry & Lab Testing
General Phone: (510) 562-7400
Email: info@steephill.com
https://www.steephill.com/science
Dr. Reggie Gaudino presentation about to NM Lawmakers.
https://www.nmlegis.gov/handouts/LHHS%20101617%20Item%209%20Dr.%20Reggie%20Gaudino%20Testimony%20with%20NM%20Samples%2010_17_17.pdf

Steep Hill's sample mass requirements for R&D Testing:
- Every individual test requires---
1 gram for flowers
1 gram concentrates
2 grams for cartridges (Four 0.5g carts or two 1g carts)
4 ml for oils, liquids and butters
1 unit for edibles (must be over two grams total weight)
1 unit for topicals
Below you will find the Cannabis testing regulations for California:
https://bcc.ca.gov/law_regs/cannabis_order_of_adoption.pdf
On page 98-99 it explains the minimum amount of sample we need for compliance testing.

American Herbal Products Association (AHPA)
Address: 8630 Fenton Street, Suite 918, Silver Spring, MD 20910
Phone: 301.588.1171
Email: ahpa@ahpa.org

American Herbal Products Association (AHPA) Cannabis Committee
http://www.ahpa.org/AboutUs/Committees/CannabisCommittee.aspx

This document includes the following Recommendations for Regulators:
• Laboratory Operations
http://www.ahpa.org/Portals/0/PDFs/Committee/CC/Cannabis_Laboratory_Recommendations_Regulators.pdf?ver=2016-02-23-150853-300

AgriScience Labs
o: 303-292-3800
a: 2120 S Birch St Denver, CO 80222
You can find our regulations at https://www.sos.state.co.us/CCR/GenerateRulePdf.do?ruleVersionId=8439&fileName=1%20CCR%20212-3 . It begins on page 175.

Here are the limits we need for testing: https://hubs.ly/H0mzflw0

http://agrisciencelabs.com/

In Conclusion:
Unfortunately 2019 has been a rough year for the state medical cannabis program participants. Please keep the focus on cannabis policy in 2020 on the medical cannabis program and protecting the program like Governor Lujan Grisham has promised. There has also not been any state legislator that has informed the patient community of any legislation to address any of these problems in the medical cannabis program, once more this past year the patients voice has been ignored.

The state has three medical cannabis laws, all three have multiple violations being allowed to occur in 2019 and now; and all of these violations are being ignored by the State of New Mexico.

1.Medical Cannabis in School Law was improperly enacted by the Public Education Department (SB-204) and the law is not being followed. Kids are still being discriminated against by the schools.

- 'Dad pleads for medical cannabis' | Friday, November 22nd, 2019 | ABQ Journal | https://www.abqjournal.com/1394537/dad-pleads-for-medical-cannabis.html

- 'Gov. candidates disagree on medical cannabis at school' | ABQ Journal | https://www.abqjournal.com/1240091/gov-candidates-disagree-on-parcc-other-education-issues.html

- "The PED, APS, Rio Rancho, and schools across the state are all disciplining students and their families, as they are denying eligibility to attend school by not allowing for a reasonable accommodation necessary for the student to attend school."

'Fix medical pot before going recreational' | Jan. 2020 | ABQ Journal | https://www.abqjournal.com/1409174/fix-medical-pot-before-going-recreational.html

2. "Adequate Supply" and "Purpose of the act" in the original The Lynn And Erin Compassionate Use Act are not being followed.
The fact of the matter with the New Mexico medical cannabis program plant count being decreased from 2500 cannabis plants to 1750 cannabis plants in 2019, that was done as a means of price control, period. It had nothing to do with "Adequate Supply", as the medical cannabis program law demands.

The Program has over 80,000 participants and the program grows less than 40,000 cannabis plants that clearly is not "adequate supply".

A research assessment of physical and pharmacokinetic relationships in cannabis production and consumption in New Mexico hasn't ever been done in relation to Equivalency in Portion and Dosage for the medical cannabis program for establishing a plant count to provide "Adequate Supply".
Here is one Colorado has done:
https://www.colorado.gov/pacific/sites/default/files/MED%20Equivalency_Final%2008102015.pdf

3. The Dept. of Health, MCP Office, and the MCAB did not fulfill their duties and responsibilities for the LECUA law (2007) in 2019.
The advisory board shall convene at least twice per year. Nor were the Public hearing responsibilities followed or fulfilled for the MCAB hearing as outlined in law and Rules & Regs. The chairperson did not conduct a fair and impartial proceeding, did not assure that the facts were fully elicited and now the hearing completion is delayed.

- 'Cannabis advisory board meeting unable to address qualifying conditions due to lack of quorum' By Andy Lyman | NM Political Report | December 10, 2019 | https://nmpoliticalreport.com/2019/12/10/cannabis-advisory-board-meeting-unable-to-address-qualifying-conditions-due-to-lack-of-quorum/

Governor Lujan Grisham has said that she wants the medical cannabis program protected before recreational cannabis legalization. And that is exactly where the focus should be - on the medical cannabis program.

More concerning is the fact that the Governor's Legalization Work Group Recommendations Open The Door To Federal Interference. The US Senate sent President Trump the Fiscal Year 2020 spending legislation that continues a budget rider protecting state medical cannabis laws from federal interference. Congressional negotiators cut House-passed measures protecting all state cannabis laws from federal interference and cut the measure allowing cannabis banking from 2020 spending legislation. The bill also continues a budget rider blocking Washington, D.C. from spending its own money to regulate recreational cannabis sales.

Medical cannabis patients in New Mexico and the state of New Mexico may find themselves without those federal protections as the Governor's Legalization Work Group recommends adopting a totally

new model for a joint medical-adult use program in New Mexico.

Those federal CJS Medical Cannabis budget rider protections do not apply to a joint medical-adult use program laws. This would also have a devastating impact on the new medical cannabis in schools law, if the state is not protected from Federal interference.

- Read more about this at: 'Governor's Legalization Group Recommendations Open The Door To Federal Interference' | Cannabis News Journal | http://www.cannabisnewsjournal.co/2019/12/governors-legalization-group.html

This is exactly why the medical cannabis program laws need to be separate from any proposed legalization legislation in New Mexico for 2020.

Using the state's medical cannabis program to create a recreational cannabis program will result in great harm coming to the state's medical cannabis program, Americans For Safe Access policy expertise advises that any system of regulation should not be built on the backs of current medical cannabis laws.

Issues such as access, police harassment, and the price and quality of medicine will still be relevant to the patient community despite the adoption of a policy of legalization for recreational use. The federal refusal to recognize the medical efficacy of cannabis causes more harm and difficulty for patients than any failure by local or state governments to adopt policies of legalization of cannabis for recreational use. Any system of regulation should not be built on the backs of current medical cannabis laws.

The legalization of cannabis for recreational use is a separate issue from safe and legal access to cannabis for therapeutic use. Americans For Safe Access cautions policy makers against letting the debate surrounding the legalization of cannabis for recreational use obscure the science and policy regarding the medical use of cannabis.

To learn more about Safe Access New Mexico please view our Community Report here:
'Safe Access New Mexico 2019 Community Advocacy Report' | Cannabis News Journal |
http://www.cannabisnewsjournal.co/2019/11/safe-access-new-mexico-2019-community.html

'Policy Letter to Governor Michelle Lujan Grisham Formally Requesting Cannabis Legislation for 2020' | Cannabis News Journal | Sent Oct. 2019 |
http://www.cannabisnewsjournal.co/2019/10/policy-letter-to-governor-michelle.html

Please defer recreational cannabis to a special session in the fall of 2020, if the proponents are right about the financial gains for the state then recreational cannabis sales will easily cover the state's cost at doing the special session for legalization.

Please keep the focus on cannabis policy in 2020 on the medical cannabis program and protecting the program like Governor Lujan Grisham has promised.

Most Respectfully Yours,

Jason Barker

Sources:

'Congress sends spending deal to Trump, ending shutdown threat' | 12/19/2019 | Politico | https://www.politico.com/news/2019/12/19/senate-moves-to-avoid-shutdown-with-passage-of-spending-deal-087898

'House-Passed Marijuana Amendments Stripped From Congressional Spending Bills' | December 16, 2019 | https://www.marijuanamoment.net/house-passed-marijuana-amendments-stripped-from-congressional-spending-bills/

'The House of Representatives approved Fiscal Year 2020 spending legislation that continues a rider protecting state medical cannabis laws from federal interference but also blocks Washington, D.C. from spending its own money to legalize marijuana sales.' | https://www.politico.com/news/2019/12/17/house-passes-massive-deal-to-fund-government-and-avoid-shutdown-086514

"The PED, APS, Rio Rancho, and schools across the state are all disciplining students and their families, as they are denying eligibility to attend school by not allowing for a reasonable accommodation necessary for the student to attend school."
'Fix medical pot before going recreational' | Jan. 2020 | ABQ Journal | https://www.abqjournal.com/1409174/fix-medical-pot-before-going-recreational.html

"We do enabling legislation and it's up to the districts to do the right thing, and in this instance they've done the opposite of the right thing," he said. "They've abused their authority and discretion to deny kids an education, period."
'Legislators could strip school districts of discretion over medical cannabis in schools' | NM Political Report | https://nmpoliticalreport.com/2019/10/28/legislators-could-strip-school-districts-of-discretion-over-medical-cannabis-in-schools/

'Policy Letter Seeks Executive Order By New Mexico's Governor For Medical Cannabis in School Law' | Cannabis New Journal | Sent Oct. 2019 | http://www.cannabisnewsjournal.co/2019/10/policy-letter-seeks-executive-order-by.html

'Legislators pushing for revisions to medical marijuana in school law' | KRQE 13 | https://www.krqe.com/news/health-news/legislators-pushing-for-revisions-to-medical-marijuana-in-school-law/

'APS medical pot directive: Parents must dose kids at school' Sept. 2019 | ABQ Journal | https://www.abqjournal.com/1364958/aps-medical-pot-directive-parents-must-dose-their-kids.html

'Who should administer cannabis in schools?' | Rio Rancho Observer | https://www.abqjournal.com/1372600/who-should-administer-cannabis-in-schools.html

"I'm disappointed and dismayed at how this was implemented," Sen. Antoinette Sedillo Lopez, D-Albuquerque, said during a hearing at the Capitol."
'Legislators may revisit law on medical cannabis at school' Oct. 2019 | ABQ Journal | https://www.abqjournal.com/1382766/legislators-may-revisit-school-cannabis-law.html

'No medical cannabis at schools despite new state law' | KOAT 7 | https://www.koat.com/article/no-medical-cannabis-at-schools-despite-new-state-law/28791724

'Medical marijuana advocates concerned over recreational cannabis proposals' | KOB 4 News | https://www.kob.com/albuquerque-news/medical-marijuana-advocates-concerned-over-recreational-cannabis-proposals/5530502/

"But the parts of the law that are supposed to protect patients from losing their jobs solely for being a patient in the program may also be hindering the nearly 79,000 cannabis patients in New Mexico from getting a job with the state. That's because the law also protects employers by giving them enough autonomy to fire or not hire a cannabis patient for safety concerns or if the employer could lose federal funding for hiring a cannabis user."
'State job opportunities limited for medical cannabis patients' Dec. 2019 | NM Political Report | https://nmpoliticalreport.com/2019/12/06/state-job-opportunities-limited-for-medical-cannabis-patients/

"Josh McCurdy with the New Mexico Medical Cannabis Patients Advocate Alliance said the state should focus on making sure patients in rural areas have access to cannabis before branching out to recreational legalization. McCurdy lives in Ruidoso and said many dispensaries in his area have a hard time keeping up with demand."
'Mixed responses to suggestions from marijuana legalization work group' | NM Political Report | https://nmpoliticalreport.com/2019/10/17/mixed-responses-to-suggestions-from-legalization-work-group/

"If lawmakers in New Mexico are going to take on the failed war on drugs, then please finish what you started with medical cannabis. Please focus on how the Medical Cannabis in Schools law passed this year is being ignored by the Public Education Department and all the schools that are keeping kids who are medical cannabis patients from being able to attend their school."
'Work group's plan will devastate medical pot' | ABQ Journal | https://www.abqjournal.com/1383936/work-groups-plan-will-devastate-medical-pot.html?fbclid=IwAR0aBEuhgvrS4FKSeEPROpHUaMOCJNmIpYBXv1_d8mJtXcvME8zQy7UpQXQ

'NM drinking water is the wrong source to irrigate pot farms' | Albuquerque Journal | Tuesday, January 14th, 2020 at 12:02am | https://www.abqjournal.com/1409520/nm-drinking-water.html

"New Mexico as it stands just does not have the logistics for recreation, said Chad Lozano, secretary of the New Mexico Medical Cannabis Patients Advocate Alliance."
'Medical cannabis experts caution against New Mexico's push to legalize recreationally' | ABC 7 KVIA | https://kvia.com/news/2019/12/23/medical-cannabis-experts-caution-against-new-mexicos-push-to-legalize-recreationally/

'Advocates petition to allow medical cannabis to be administered to animals' | Dec. 2019 | KOB 4 | https://www.kob.com/albuquerque-news/advocates-petition-to-allow-medical-cannabis-to-be-administered-to-animals/5574622/?cat=500

"Board stalls on medical marijuana policy"
'RRPS wrestling with bus deficits, medical pot' | Nov. 2019 | ABQ Journal | https://www.abqjournal.com/1387944/rrps-wrestling-with-bus-deficits-medical-pot.html

'Medical marijuana users struggle to keep up with costs' | Nov. 2019 | ABQ Journal | https://www.abqjournal.com/1386640/medical-marijuana-users-struggle-to-keep-up-with-costs.html
The school district is now breaking the law by failing to meet the "reasonable accommodation" aspect of the law by forcing parents to come to school when school personnel need to be doing their job and handling the student's medication needs.
'Social Equity and New Mexico's Medical Cannabis in Schools Law' | Cannabis News Journal | http://www.cannabisnewsjournal.co/2019/09/social-equity-and-new-mexicos-medical.html
'Aztec school board approves medical cannabis policy for students' | FDT | https://www.daily-times.com/story/news/2019/12/20/medical-marijuana-policy-approved-for-aztec-schools-students/2690991001/

"A person who is serving a period of probation or parole or who is in the custody or under the supervision of the state or a local government pending trial as part of a community supervision program shall not be penalized for conduct allowed under the Lynn and Erin Compassionate Use Act." NM Stat § 26-2B-10"
'Medical cannabis patient asks judge to allow cannabis on house arrest' By Andy Lyman | NM Political Report | Jan. 2020 | https://nmpoliticalreport.com/2020/01/09/medical-cannabis-patient-asks-judge-to-allow-cannabis-on-house-arrest/

"Fifty-five percent of our producers are having trouble meeting the demand for those products already and if over half of the people in the program can't produce that quickly enough, if we roll into a recreational law then it would be a great concern for me and a lot of the other patients,"
'Medical marijuana advocates concerned over recreational cannabis proposals' | KOB 4 News | https://www.kob.com/albuquerque-news/medical-marijuana-advocates-concerned-over-recreational-cannabis-proposals/5530502/?cat=500

"Under the new fee schedule, it will be impossible for all producers to meet the 1,750 maximum and cultivate an adequate supply of medicine for patients,"
'Cannabis producer says state is pricing out smaller producers, limiting access to medicine' | NM Political Report | https://nmpoliticalreport.com/2019/10/21/cannabis-producer-says-state-is-pricing-out-smaller-producers-limiting-access-to-medicine/
"the fact that Lujan Grisham's group recommends the state subsidize medical marijuana through the recreational market — if one is approved — and supply the medical market first, doesn't cut it.
The $180,000 in annual fees for growing the maximum amount is far too prohibitive for most growers, he said, and until medical marijuana is covered through Medicaid and private health insurance, patients will always be at risk of a supply shortage. But he sees the cap on plants per producer as the biggest problem."
'Medical pot producer sees hole in New Mexico legalization report' | Santa Fe New Mexican | https://www.santafenewmexican.com/news/local_news/medical-pot-producer-sees-hole-in-new-mexico-legalization-report/article_e7e0e4d0-2ccf-5dbc-8127-c4b30fd134e8.html

'Students who depend on medical cannabis one step closer to getting it at school' | Aug. 2019 | KOAT 7 | https://www.koat.com/article/school-districts-to-decide-how-medical-cannabis-will-be-administered-to-students/28836362

'Homework for PED: Make rules match law on medical pot' | ABQ Journal | https://www.abqjournal.com/1350592/homework-for-ped-make-rules-match-law-on-medical-pot.html

'New Mexico is now the 8th Medical Cannabis State to allow Safe Access to Medical Cannabis at Schools' | April 11, 2019 | Americans For Safe Access | https://www.safeaccessnow.org/new_mexico_is_now_the_8th_medical_cannabis_state_to_allow_safe_access_to_medical_cannabis_at_schools

"Legislators listened at a public hearing as University of New Mexico economics professor Sarah Stith cautioned against legalization measures that might make retail prices uncompetitive with Colorado's recreational market, through restrictions on supplies or excessive taxation."
'Some Democrats, Including Papen, Not Yet Endorsing Marijuana Legalization' | KRWG https://www.krwg.org/post/some-democrats-including-papen-not-yet-endorsing-marijuana-legalization
'Dad pleads for medical cannabis' | Friday, November 22nd, 2019 | ABQ Journal | https://www.abqjournal.com/1394537/dad-pleads-for-medical-cannabis.html

'Gov. candidates disagree on medical cannabis at school' | ABQ Journal | https://www.abqjournal.com/1240091/gov-candidates-disagree-on-parcc-other-education-issues.html

'Cannabis advisory board meeting unable to address qualifying conditions due to lack of quorum' By Andy Lyman | NM Political Report | December 10, 2019 | https://nmpoliticalreport.com/2019/12/10/cannabis-advisory-board-meeting-unable-to-address-qualifying-conditions-due-to-lack-of-quorum/

'So Tired of Still Fighting for Medical Cannabis Rights' | National Pain Report | 07.28.2019 | http://nationalpainreport.com/so-tired-of-still-fighting-for-medical-cannabis-rights-8840612.html

'Governor's Legalization Group Recommendations Open The Door To Federal Interference' | Cannabis News Journal | http://www.cannabisnewsjournal.co/2019/12/governors-legalization-group.html

"On a Sunday afternoon over Labor Day weekend, a masked man, armed with a gun, burst through the doors of an Albuquerque medical cannabis dispensary. About two minutes later, he walked back out the door, with an estimated $5,000 worth of cannabis products. In that time, the man hopped over a glass display case and corralled employees and at least one patient into one spot while he emptied a large jar of cannabis—and seconds later cannabis concentrates from the display case—into a bag. After he left, the man got into a car waiting in the back and sped off. All of it was caught on security cameras."
'NM leaves med. cannabis security specifics up to producers' Nov. 2019 | NM Political Report | https://nmpoliticalreport.com/2019/11/18/nm-leaves-med-cannabis-security-specifics-up-to-producers/

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Safe Access New Mexico
[redacted]

Americans For Safe Access - Member
American Cannabis Nurses Association - Member
[redacted]

The American Medical Association has no objection to any reasonable regulation of the medicinal use of cannabis and its preparations and derivatives. It does pretest, however, against being called upon to pay a special tax, to use special order forms in order to procure the drug, to keep special records concerning its professional use and to make special returns to the Treasury Department officials, as a condition precedent to the use of cannabis in the practice of medicine."
~Wm. C. Woodward, Legislative Counsel - 11:37 AM Monday, July 12, 1937

[EXT] Regulations update

Erik Burr <erik@naturesforceorganics.com>

Thu 1/16/2020 10:50 AM

To: comment, MCP, DOH <MCP.Comment@state.nm.us>;

To whom it may concern,
1) I am writing you today in support of FULL SPECTRUM TESTING (FST) requirements to sell cannabis. FST is the backbone of both Medical and Recreational programs. Are you aware of the amount of pesticides being used within the NMMCP? Its rampant and patients do not have any avenues to determine if their medicine is clean and void of any toxic materials. Additionally the cannabis species is genetically coded to clean soils that contain heavy metals and other potential contaminants. The bottle nutrients widely being used and sold to LNPP's contains these elements therefore the state needs to establish full spectrum testing requirements to ensure the safety of medicine being sold to patients.
The state also owns a state run laboratory in Albuquerque which already has the majority of the equipment required. State should consider using the large amount of money the NMMCP has generated to hire accredited scientists to provide testing services to both Patients and Producers alike and provide oversight of both Scepter Labs and Rio Grande Analytics which have been inaccurate and inconsistent in testing as confirmed by LNPP's and Patients statewide.
Patients are not criminals and I realize the state has an issue with patients in this state. I find this unfortunate because the State of NM is not compliant with providing clean quality medicine via the issuance of NM State Licensed for profit Non-Profits. I fear that if the state does not take measures to correct this issue there will come a point where a patient harmed as a result of this lacking regulation by which the state will be held accountable.
Isn't it time to implement proper policy of checks and balances to ensure safety to the 80,000+ patient enrolled?? Your citizens believe it is.
2) Licenses need to be opened up. The state has created a monopolized system which is in breach of the federal government antitrust laws. As a result we have seen significant reduction in quality while simultaneously seeing and increase in costs per gram. There has to be a balance and currently the scale is overly skewed in favor of LNPP's. The state has a plethora of qualified cultivators that would bring forth a craft cannabis industry to this state. Look at what craft beer has done for NM? Would it not benefit this state to see another craft industry thrive? Creating quality products, hiring more unemployed and boosting our NM economy. ALL of which benefits the state government. NM has seen the worst of this industry. Just look at operations that continue to breach every rule and regulation of the NMMCP. NM can create a vibrant industry by opening licenses for Craft Cannabis of NM growers only. We have to stop this out of state mentality which leaves NM consistently poor. Help NM by supporting NM growers and businesses instead of out of state operations. Thank you.
3) Landlord rule should be removed. Landlords are not HIPPA certified and therefore this rule is already in breach of federal law. It is time to change this rule to the benefit of patients.
4) The limit on units is antiquated and should be removed. Patients medicate differently and therefore there should not be limits on access to the medicine they need. Think of those patients who have fought for your freedom! Many require larger units to attain the volume of medicine they require due to the trauma they have suffered. I personally know many Vets that require concentrated cannabis products in order to maintain a daily quality of life. They need you to make those changes in order to be a positive member of our society.
Thank you for allowing me and opportunity to provide input on these important subjects. I hope the information I provided today will assist your body to push for the changes to make this program better, more equitable to everyone and not just the few LNPP's.
Thank you kindly.

Thank you,

TECHNICAL REPORT:

OREGON HEALTH AUTHORITY'S PROCESS TO DETERMINE WHICH TYPES OF CONTAMINANTS TO TEST FOR IN CANNABIS PRODUCTS, AND LEVELS FOR ACTION

Author
David G. Farrer, Ph.D.
Public Health Toxicologist

Oregon Health Authority
PUBLIC HEALTH DIVISION

Technical Report: Oregon Health Authority's Process to Determine Which Types of Contaminants to Test for in Cannabis Products, and Levels for Action*

Author: David G. Farrer, Ph.D., Public Health Toxicologist

Acknowledgments

OHA would like to thank the following individuals and organizations for their valuable contributions to the development of cannabis testing Oregon Administrative Rules (OAR 333-7-0010 through 333-7-0100 and OAR 333-7-0400 and 333-7-0410 Exhibit A) and this report:

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Oregon Department of Environmental Quality

Theodore R. Bunch, Jr.
Pesticide Analytical and Response Center Coordination Leader
Oregon Department of Agriculture

Keith Crosby
Technical Director
Synergistic Pesticide Lab

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Oregon Environmental Laboratory Accreditation Program, Public Health Division, Oregon Health Authority

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Lab Director
Oregon Growers Analytical

For information on this report, contact David Farrer at David.G.Farrer@state.or.us.

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BACKGROUND

This report describes the process the Oregon Health Authority (OHA) followed to establish the list of contaminants for cannabis testing. It also describes how OHA established an action level for each of these contaminants.

These lists and action levels have now been implemented in Oregon Administrative Rules (OAR 333-7-0010 through 333-7-0100 and OAR 333-7-0400 and 333-7-0410 Exhibit A).

This report documents the rationale and justifications for:

- The selection of target contaminants for testing; and
- Testing regimes for cannabis and cannabis-derived products.

The three major categories of contaminants targeted for testing include:

- Microbiological contaminants;
- Pesticides; and
- Solvents.

OHA is committed to evidence-based decision making when drafting and implementing OARs. As research into cannabis use and safety advances, the OARs related to cannabis testing and this report will be revised and updated to reflect the state of the science.

Not all types of cannabis products need testing for all three of these contaminant categories. Below is information on each of the three major categories of contaminants targeted for testing.

In developing the OARs and this document, OHA relied on the expertise of individuals from various organizations named in the "Acknowledgments" section. Their expertise ranged from pesticide use in Oregon, pesticide regulation in Oregon, analytical chemistry, laboratory accreditation, microbiology, cannabis processing and cannabis cultivation. They also represented a range of organizations including the Oregon Department of Agriculture, commercial analytical chemistry laboratories, state laboratories and state laboratory accreditation personnel. Throughout this document, this group will be referred to as the "Technical Expert Work Group" or the "work group."

MICROBIOLOGICAL

The Technical Expert Work Group recommended that cannabis products be tested for *E. coli* and *Salmonella.* The work group also advised that products not be allowed to go to market if any *Salmonella* is detected or if *E. coli* is detected at levels higher than 100 CFU/g. In general, bacteria cannot survive either the drying or heating processes that occur when cannabis is prepared for smoking. *Salmonella,* however, can survive when very little moisture is present, and it can easily infect humans. *E. coli* does not usually pose a significant health risk; however, its presence indicates poor sanitary conditions and that other fecal bacteria may be present. Testing for both organisms in cannabis products will, therefore, protect public health.

The only other *microbial* organisms of concern on cannabis are several species of *Aspergillus* mold. *Aspergillus* can cause respiratory infections in individuals who inhale it if they are severely immune-compromised. These individuals should avoid smoking cannabis. However, OHA Administrative Rules do not require testing for *Aspergillus;* the mold is so common in the environment that a person could pick it up many different ways. A positive test result would not mean the product is unsafe for most uses for most people. Therefore, the work group recommended that cannabis products intended for smoking and other inhalation uses include a warning about this risk for people with suppressed immune systems.

Some states have required testing of cannabis for *aflatoxins* produced by certain *Aspergillus* species. Oil-rich seeds must be present to produce these toxins on plants. Commercial cannabis does not contain these seeds. As a result, the Technical Expert Work Group recommends against such testing.

Water activity

Water activity is a measure of how moist something is in units called "A_w". Most pathogenic microbial organisms cannot grow when water activity is less than A_w 0.65. Testing for water activity and requiring water activity levels to fall below A_w 0.65 will ensure the absence of microbial growth on cannabis products during storage and before sale.

PESTICIDES

Target analyte list development

Work group members established three lists of *target analytes* related to pesticides. OHA compiled the three lists and filtered it by criteria agreed upon by the work group.

- Work group members created the first list as described in Appendix 1 of a white paper titled "Pesticide Use on Cannabis" published by the Cannabis Safety Institute in June 2015.(1) This list contained 123 active ingredients.
- The work group generated the second list by identifying compounds that overlapped between various other lists. This included the first list described above; Oregon, Nevada or Colorado regulations for medical or recreational marijuana; and other lists.
- The work group generated the third list based on integrated pest management guidance for several crops grown in the Pacific Northwest. It also included a search of the Pesticide Information Center Online (PICOL) database. Additionally, work group members made a list of the active ingredients in pesticide products available at a local hardware store. Once this information was compiled, work group members compared their master list to the first two lists described above and removed any redundancies.

OHA compiled these three submitted lists and removed duplicates. This resulted in a starting list of 188 pesticide analytes.

Table 1 describes the process by which the work group scored and filtered the compiled list of 188 pesticide analytes. First, they scored active ingredients based on general (human) toxicity, analytical capacity, detection frequency in cannabis samples in Oregon and general availability. All scoring parameters were reduced to a four-point scale (from zero to three). Then, OHA added scores across the parameters to get a composite score for each pesticide active ingredient.

An OHA toxicologist initially scored active ingredients for toxicity. An Oregon State University toxicologist and an Oregon Department of Agriculture (ODA) representative with some training in toxicology reviewed and approved the toxicity scoring. Three analytical laboratories participating in the work group independently scored analytical capacity and detection frequency in Oregon's cannabis.

OHA averaged these independently submitted scores and rounded averaged analytical capacity and detection frequency scores to the nearest whole number (0.5 was rounded to 1).

ODA scored general availability based on registration status and general knowledge of use patterns. Every pesticide product must be registered for specific uses with ODA. As a result, ODA has expert knowledge on which pesticides are used for which purposes in Oregon.

Table 1. Scoring process for each target pesticide analyte on OHA's compiled list

	Low (0) → Priority to keep on list → High (3)			
	0	**1**	**2**	**3**
General toxicity	No data	*Fungicides*, plant growth regulators	Pyrethroid, neonicotinoid, pyrazole and pyrimidine, and macrocyclic lactone insecticides and *acaricides* and insect growth regulators	*Organophosphate*, organochlorinated and *carbamate* insecticides.
Analytical capability	Not tested	Expensive and/ or analytically challenging to test in cannabis	Some labs said feasible, other labs said not feasible	Multi-instrument, "easy" clean-up, all labs in agreement
Detection frequency (in cannabis)	Tested but never detected	Not tested	Single detection	Multiple detections
Availability	Not available or ODA experience suggested this analyte would not be used or detected in cannabis	Restricted use pesticide registered for a single crop or use	Restricted use pesticide registered for multiple crops or uses	General use pesticide (no license or other certification needed to purchase or use products with this active ingredient); ODA knowledge that the analyte is frequently used illegally and likely to be used on cannabis

Once scoring was complete, OHA applied an extra point to the composite score for each analyte that scored 2 or higher for detection frequency in cannabis. Detection frequency indicates this pesticide active ingredient is already being used in Oregon's cannabis. As a result, OHA placed greater emphasis on detection frequency than on other parameters in cannabis. This weighting process ensured that composite scores would reflect this emphasis on pesticides known to be used in Oregon's cannabis.

Every analyte with a composite score of 8.5 or higher was retained on the final list. Analytes with composite scores below 8.5 were removed from the list. OHA selected 8.5 as the cutoff score because it was the highest score that captured all pesticide active ingredients that had ever been detected in cannabis in Oregon.

Pesticides, continued

After filtering out all analytes with a score lower than 8.5, OHA addressed work group experts' special requests.

- First, ODA and analytical laboratory representatives recommended not including any *organochlorine* insecticides on the list. For the most part, these compounds have been banned for decades. Any *organochlorine* contamination would be at low levels due to historical uses in the area from decades ago as opposed to direct, recent application to cannabis. This request removed *chlordane* from the list of target analytes.
- Second, commercial analytical laboratory representatives recommended adding etoxazole, fenpyroximate, fludioxonil, methiocarb, methomyl, MGK-264, oxamyl, propiconazole, spinosad, spiromesifen, spirotetramat, thiacloprid and trifloxystrobin to the list of target analytes. This request was based on Technical Expert Work Group members' special knowledge of cannabis grower practices and potential for use of these compounds.
- Third, with two exceptions (piperonyl butoxide and pyrethrins) OHA removed analytes from the list that will be included in ODA's list of pesticides that may be allowed for use on cannabis. This step removed azadirachtin from the target analyte list for pesticides. Piperonyl butoxide and pyrethrins may be allowed for use on cannabis. However, they remain on the target analyte list because of potential for misuse. OHA counterparts in Colorado, where some marijuana has already been tested for pesticide residues, reported to OHA that they have found very high concentrations of piperonyl butoxide (up to 50 parts per million [ppm]) in *cannabinoid* concentrates. They also report that piperonyl butoxide and pyrethrins are typically used together.

The resulting target analyte list, shown as Table 2, includes 59 target analytes along with their action levels.

Developing action levels

OHA set action levels for pesticide active ingredients based on presence/absence. Analytical chemistry laboratories can only certify the absence of an analyte down to each laboratory's limit of quantification (LOQ). Therefore, OHA set action levels based on presence/absence listed as a reasonable LOQ that accredited laboratories should be able to achieve.

Ideally, action levels would be based on human health and toxicity thresholds. However, health risk from pesticides results from a combination of:

- The inherent toxicity of the pesticide; and
- The level of exposure to the pesticide people have.

OHA has a lot of information about the inherent toxicity of pesticide active ingredients. However, OHA does not currently have enough information about exposure levels to pesticides from the various uses of contaminated cannabis products. Therefore, OHA could not base action levels on health risk and instead set them on LOQs; OHA based the criterion for pass/fail on whether or not an analyte is detected above the action level. Cannabis samples with pesticide active ingredients detected above the action level fail and the product must be destroyed.

To set action levels, OHA asked commercial analytical laboratories to submit their LOQs for each analyte on the target list in cannabis. Two labs submitted LOQs, while a third lab submitted limits of detection on the instrument types from published literature. For each instrument type, OHA multiplied the higher of the LOQs from the two laboratories by a factor of 2 to generate the action level. There were some analytes that no labs in Oregon had experience testing in cannabis, so there were no LOQs to submit. In those cases, OHA selected the highest action level from among analytes with the same published detection limits for the relevant analytical laboratory equipment.

Piperononyl butoxide and pyrethrins are on both OHA's target analyte list and ODA's list of pesticides that may be allowed on cannabis. OHA adopted Nevada's action levels for these analytes. Nevada's action level for piperonyl butoxide is based on its state laboratory's limit of quantification for this compound in the cannabis matrix. The Nevada lab's action level of 1 ppm for pyrethrins is based on the lowest federal food tolerance for pyrethrins in edible plant material. The Washington Department of Health is also adopting Nevada's action levels for these two compounds. OHA adopted Nevada's action levels primarily to be consistent with policies in neighboring states.

Uncertainties

- Scoring system for pesticides – No scoring system is perfect. Each category of scoring has areas of uncertainty where professional judgment was applied.
    - » Toxicity scoring – The toxicity of pesticide active ingredients is highly variable within classes and dependent upon other compounds included in the final product formulation. No scoring system can perfectly condense the complexity of pesticide toxicology into a four-point ranking system. Some *fungicides* may, for instance, be more acutely toxic than some *organophosphate* pesticides. The work group did not have time or resources for an in-depth assessment of each active ingredient in all its formulations. Rather, compounds were ranked based on chemical class. This assumes that, generally, insecticides and *acaricides* are more toxic to mammals than *fungicides* and plant growth regulators. In addition, *organophosphate*, *organochlorine* and *carbamate* insecticides will generally be more toxic than other insecticide classes. OHA and OSU toxicologists agreed that this rough ranking system was adequate for the purpose of screening and prioritizing active ingredients for inclusion in the target analyte list.

Pesticides, continued

  - » Analytical capacity – This scoring relied heavily on the professional judgment and experience of the analytical chemists on the work group. This parameter was difficult to score because ease of analysis is highly dependent on the type of equipment used and extraction methods necessary for that instrument. Chemists on the work group tried to remain objective regarding the type of equipment used.
  - » Detection frequency – This was the most straightforward parameter to score. Laboratory representatives in the work group reported whether they had or had not detected or tested for each contaminant in cannabis samples.
  - » Availability – This parameter had less uncertainty than other scoring categories. It was generally based on registration status augmented with ODA's knowledge of which pesticides are commonly used illegally and likely used on cannabis.
- Action levels
  - » Because cannabis recently became legal in three states, scant research exists on exposure to establish toxicity-based tolerances for pesticide residues in cannabis products. The variety of uses and exposure routes is too great. There is also not enough information about the *pyrolysis* products of target pesticides relevant to cannabis products when smoked.
  - » Some analytes in cannabis have not been tested in cannabis by any Oregon analytical laboratory. For these analytes, OHA used *surrogate analytes* with similar published detection limits. This is not ideal, but represents the best available estimate at this time. Administrative Rules requiring that labs submit their LOQs along with sample results will allow OHA to update action levels in Administrative Rule based on data as appropriate in the future.

Table 2. Pesticide analytes and their action levels

Analyte	Chemical Abstract Services (CAS) Registry number	Action level ppm
Abamectin	71751-41-2	0.5
Acephate	30560-19-1	0.4
Acequinocyl	57960-19-7	2
Acetamiprid	135410-20-7	0.2
Aldicarb	116-06-3	0.4
Azoxystrobin	131860-33-8	0.2
Bifenazate	149877-41-8	0.2
Bifenthrin	82657-04-3	0.2
Boscalid	188425-85-6	0.4
Carbaryl	63-25-2	0.2
Carbofuran	1563-66-2	0.2
Chlorantraniliprole	500008-45-7	0.2
Chlorfenapyr	122453-73-0	1
Chlorpyrifos	2921-88-2	0.2
Clofentezine	74115-24-5	0.2
Cyfluthrin	68359-37-5	1
Cypermethrin	52315-07-8	1
Daminozide	1596-84-5	1
DDVP (Dichlorvos)	62-73-7	0.1
Diazinon	333-41-5	0.2
Dimethoate	60-51-5	0.2
Ethoprophos	13194-48-4	0.2
Etofenprox	80844-07-1	0.4
Etoxazole	153233-91-1	0.2
Fenoxycarb	72490-01-8	0.2
Fenpyroximate	134098-61-6	0.4
Fipronil	120068-37-3	0.4
Flonicamid	158062-67-0	1
Fludioxonil	131341-86-1	0.4
Hexythiazox	78587-05-0	1
Imazalil	35554-44-0	0.2
Imidacloprid	138261-41-3	0.4
Kresoxim-methyl	143390-89-0	0.4
Malathion	121-75-5	0.2
Metalaxyl	57837-19-1	0.2
Methiocarb	2032-65-7	0.2
Methomyl	16752-77-5	0.4
Methyl parathion	298-00-0	0.2
MGK-264	113-48-4	0.2
Myclobutanil	88671-89-0	0.2
Naled	300-76-5	0.5
Oxamyl	23135-22-0	1
Paclobutrazol	76738-62-0	0.4
Permethrins*	52645-53-1	0.2
Phosmet	732-11-6	0.2
Piperonyl_butoxide	51-03-6	2
Prallethrin	23031-36-9	0.2
Propiconazole	60207-90-1	0.4
Propoxur	114-26-1	0.2
Pyrethrins†	8003-34-7	1
Pyridaben	96489-71-3	0.2
Spinosad	168316-95-8	0.2
Spiromesifen	283594-90-1	0.2
Spirotetramat	203313-25-1	0.2
Spiroxamine	118134-30-8	0.4
Tebuconazole	80443-41-0	0.4
Thiacloprid	111988-49-9	0.2
Thiamethoxam	153719-23-4	0.2
Trifloxystrobin	141517-21-7	0.2

* Permethrins should be measured as cumulative residue of cis- and trans-permethrin isomers (CAS numbers 54774-45-7 and 51877-74-8).

† Pyrethrins should be measured as the cumulative residues of pyrethrin 1, cinerin 1 and jasmolin 1 (CAS numbers 121-21-1, 25402-06-6, and 4466-14-2 respectively).

Pesticides, continued

SOLVENTS

Background

Some producers of cannabis products use solvents to extract and/or concentrate the active ingredients from cannabis. Similar processes are also used to produce other pharmaceutical products. The Oregon Health Authority (OHA) adopted a list of target solvent analytes to be applied to cannabis extracts and concentrates (Table 3). The purpose of testing for these solvents and common solvent contaminants is to ensure that these compounds, if present, do not exceed levels that would be expected to harm cannabis users' health.

Target analyte list development

A work group member representing a laboratory that does testing for residual solvents in other pharmaceuticals created the list that OHA adopted. This work group member is also familiar with common extraction and concentration techniques and solvents used in Oregon's cannabis industry.

Developing action levels

The action levels are based on the "International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, ICH Harmonized Tripartite Guideline, Impurities: Guideline for Residual Solvents Q3C(R5)" (ICH Q3C).(2) The only solvents commonly used in the cannabis industry for which no action levels have been established are *butane, propane, 2-methylbutane, methylpropane, 2,2-dimethylbutane, 2,3-dimethylbutane, 2-methylpentane and 3-methylpentane.*

Butane, propane, 2-methylbutane and methylpropane are short-chain alkanes similar to pentane. Pentane falls into a class of solvents designated as class 3 by ICH Q3C. Class 3 solvents are less toxic and default to a health-based action level of 5,000 ppm residual. Because of the similarities to pentane, OHA assigned action levels of 5,000 ppm for butane, propane, 2-methylbutane and methylpropane.

OHA assigned *n-hexane's* action level of 290 ppm as the action level for 2,2-dimethylbutane, 2,3-dimethylbutane, 2-methylpentane and 3-methylpentane because they are *isomers* of *n-hexane*.

The health-based action levels in the ICH Q3C are based on the toxicity of the individual solvent and on the magnitude of exposure likely to occur from consuming 10 grams of the pharmaceutical. Ten grams is a health-protective assumption. It is unlikely that anyone would consume more than 10 grams of cannabis extract or concentrate in a single day.

Uncertainties

- Action levels
  - » No health-based solvent residual limits have been established specifically for cannabis extract or concentrate products. However, practices around pharmaceutical production and limits provide a reasonable model. This especially pertains to the oral consumption of cannabis products.
  - » We are uncertain whether the selected action levels for solvents in cannabis products sufficiently protect persons who smoke cannabis. However, the ICH Q3C does assume 100% absorption by any exposure route. This covers inhalation, which is how some pharmaceuticals are administered.

Table 3. List of solvents and their action levels

Solvent	Chemical Abstract Services (CAS) Registry number	Action level (µg/g)
1,2-Dimethoxyethane	110-71-4	100
1,4-Dioxane	123-91-1	380
1-Butanol	71-36-3	5000
1-Pentanol	71-41-0	5000
1-Propanol	71-23-8	5000
2-Butanol	78-92-2	5000
2-Butanone	78-93-3	5000
2-Ethoxyethanol	110-80-5	160
2-methylbutane	78-78-4	5000*
2-Propanol (IPA)	67-63-0	5000
Acetone	67-64-1	5000
Acetonitrile	75-05-8	410
Benzene	71-43-2	2
Butane	106-97-8	5000*
Cumene	98-82-8	70
Cyclohexane	110-82-7	3880
Dichloromethane	75-09-2	600
2,2-dimethylbutane	75-83-2	290†
2,3-dimethylbutane	79-29-8	290†
1,2-dimethylbenzene	95-47-6	See Xylenes
1,3-dimethylbenzene	108-38-3	See Xylenes
1,4-dimethylbenzene	106-42-3	See Xylenes
Dimethyl sulfoxide	67-68-5	5000
Ethanol	64-17-5	5000
Ethyl acetate	141-78-6	5000
Ethylbenzene	100-41-4	See Xylenes
Ethyl ether	60-29-7	5000
Ethylene glycol	107-21-1	620
Ethylene Oxide	75-21-8	50
Heptane	142-82-5	5000
n-Hexane	110-54-3	290
Isopropyl acetate	108-21-4	5000
Methanol	67-56-1	3000
Methylpropane	75-28-5	5000*
2-Methylpentane	107-83-5	290†
3-Methylpentane	96-14-0	290†
N,N-dimethylacetamide	127-19-5	1090
N,N-dimethylfromamide	68-12-2	880
Pentane	109-66-0	5000
Propane	74-98-6	5000*
Pyridine	110-86-1	200
Sulfolane	126-33-0	160
Tetrahydrofuran	109-99-9	720
Toluene	108-88-3	890
Xylenes‡	1330-20-7	2170

* Limit based on similarity to pentane.

† Limit based on similarity with n-hexane.

‡ Combination of: 1,2-dimethylbenzene, 1,3-dimethylbenzene, 1,4-dimethylbenzene, and ethyl benzene.

Solvents, continued

REFERENCES

1. Voelker R, Holmes M. *Pesticide use on cannabis.* Cannabis Safety Institute. 2015 June. Available at http://cannabissafetyinstitute.org/wp-content/uploads/2015/06/CSI-Pesticides-White-Paper.pdf.

2. International Council for Harmonisation. European Medicines Agency. *ICH Guideline* Q3C (R5) on impurities: Guideline for residual solvents. 2015 September. Available at www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2011/03/WC500104258.pdf.

DEFINITIONS

Unless otherwise noted, definitions were provided by the author.

***acaricides*:**
Pesticides that kill members of the arachnid subclass acari, which includes ticks and mites.

action level:
The level of a contaminant (pesticide or solvent) that, if found in a cannabis product, triggers agency action to prohibit that cannabis product from being sold.

aflatoxins:
A group of chemically similar fungal metabolites produced by certain strains of molds in the genus *Aspergillus*. They are a subset of the larger class of fungal metabolic toxins known as mycotoxins.

analyte (from http://dictionary.reference.com/browse/analyte):
A substance or chemical component that is undergoing analysis.

Aspergillus (from "American Heritage Dictionary"):
Any of various fungi of the genus *Aspergillus*, which includes many common molds.

A_w: See "Water activity" definition.

cannabinoid:
A class of chemicals, unique to cannabis (marijuana), derived from cannabigerolic acid and known to interact with cannabinoid receptors.

carbamate:
A class of pesticides derived from carbamic acid that inhibits the acetylcholine esterase enzyme in the target species.

CFU/g:
Colony forming units per gram. Refers to a measure of the amount of living bacteria per given amount (1 gram) of a sample.

E. coli *(Escherichia coli)**:***
A species of bacteria found in large quantities in the human digestive tract. Presence of *E. Coli* can indicate fecal contamination.

fungicide:
A chemical pesticide designed to kill or prevent the growth of fungus.

isomer:
A molecule with the same chemical formula as another molecule, but with a different chemical structure.

limit of quantification (from www.ncbi.nlm.nih.gov):
The lowest concentration at which the analyte can not only be reliably detected but at which some predefined goals for bias and imprecision are met.

microbial (from "Stedman's Medical Dictionary"):
Relating to any minute organism.

microbiological (from "Stedman's Medical Dictionary"):
Concerned with microorganisms, including fungi, protozoa, bacteria and viruses.

organochlorine (from "American Heritage Dictionary" with modifications):
Any of various hydrocarbon (containing carbon and hydrogen) pesticides, such as DDT, that contain chlorine as the dominant functional group.

***organophosphate*:**
Any of several organic chemicals that contain an *organophosphate* or organo-thiophosphate ester as the primary functional group, some of which are used as fertilizers and pesticides. For more information on ester, go to www.merriam-webster.com/dictionary/ester.

Definitions, continued

pyrolysis (from "American Heritage Dictionary"):
Decomposition or transformation of a compound caused by fire.

Salmonella:
A species of bacteria that causes illness in humans.

solvent:
A substance that can dissolve another substance, or in which another substance is dissolved, forming a solution. For example, water can be used as a solvent to dissolve salt. In chemistry, various solvents are used to extract a chemical of interest from the substance in which it is naturally found. In the case of cannabis, some processors use solvents to dissolve THC (the active ingredient in marijuana) so it can be extracted or separated from the cannabis plant.

surrogate analyte:
Surrogates are compounds similar in chemical composition to the analytes of interest and spiked into environmental samples prior to preparation and analysis. They are used to evaluate extraction efficiency and matrix interference on a sample-specific basis. In some settings a surrogate analyte that is easy to measure may be used as a substitute to estimate the concentration or presence of another analyte that is difficult to measure but often co-occurs with the surrogate.

target analyte:
A chemical the lab must test for to see if it is present in cannabis.

water activity (or A_w):
The partial vapor pressure of water in a substance divided by the standard state partial vapor pressure of water.

Definitions, continued

Technical report:

Oregon Health Authority's process to determine which types of contaminants to test for in cannabis products, and levels for action

The marijuana universal symbol means a product contains marijuana and should be kept in its original packaging, out of the reach of children.

Oregon Health Authority
PUBLIC HEALTH DIVISION

OHA 8964 (01/2016)

[EXT] Oregon Guidance

Greg Miller <doctor.arsenic@gmail.com>

Thu 1/16/2020 10:58 AM

To: comment, MCP, DOH <MCP.Comment@state.nm.us>;

1 attachment

oha-8964-technical-report-marijuana-contaminant-testing.pdf;

Analytical requirements should be developed this way.

Greg

[EXT] Public Comment Submission (1/16/20)

High Desert Relief <hdrelief@gmail.com>

Thu 1/16/2020 11:28 AM

To: comment, MCP, DOH <MCP.Comment@state.nm.us>;

Dear Medical Cannabis Program,

Please accept the following written comments pertaining to the proposed rule changes regarding NMAC 7.34.4. Our comments are in regards to efforts to continue in the path for providing the utmost in patient safety, but also being conscientious when it comes to the implementation of these changes to help maintain superb medicine pricing and not being redundant or wasteful.

7.34.4.9(5) HEAVY METALS TESTING
7.34.4.9(6) PESTICIDE TESTING
It has been proven that cannabis grown indoors in artificial media will not produce heavy metals. Our LNPP does not use any pesticides in the production of medical cannabis. Therefore, we think these two tests should be done on a random basis as designated by the Department, but not mandated on every sample. Please also consider allowing an exemption to these tests if there is a 100% consistent pattern of negative (or zero presence of heavy metals/pesticides) results shown in the randomized testing. Additionally, because of the new instruments and new methodology required to implement these new tests is so costly, one of the state approved labs reported that it would add an increase of $600 to each full panel test which would make it burdensome and may adversely affect the cost of patient medicine.

7.34.4.16(C) LABELING OF USABLE CANNABIS; DRUG INFORMATION SHEETS:
We feel as though most of the information required on the new labeling requirements are identical to the proposed 'Drug Information Sheets' and will be redundant and wasteful. We are hopeful that the Medical Cannabis Program will consider consolidating the additional information required on the separate Drug Information Sheet, be added to the product labeling of usable cannabis so only one document is required per item.

In addition to the slight cost increase per transaction that may ensue by requiring two documents per transacted item, if we are able to consolidate the information on to one document, we believe that it will be more effective in relaying the information. The consolidation of the pertinent information on a product label will also prevent the abundant and projected discarding of the separate Drug Information Sheets by the qualified patients/care givers.

Finally, since our seed-to-sale tracking software provider BioTrack has not shown the capabilities to be able to produce these enhanced labels with all of the required information, we recommend that the MCP first mandate that BioTrack provides this capability to produce this information on a label before it is implemented.

Thank you for allowing us to comment of the proposed rule changes and we hope these suggestions are helpful in crafting the final regulations.

In service,
Drew Stuart
High Desert Relief

[EXT] Open the license

[redacted]

Thu 1/16/2020 10:57 PM

To: comment, MCP, DOH <MCP.Comment@state.nm.us>;

I am a medical patient and a PPL grower we need proper growing proper testing we need more licensing so it's cheaper for people like me and my wife are on disability to afford our medications we need to allow the PPLs to sell to the dispensaries or patient's because we are not necessarily about the money we are about the patient and quality of the medicine

2019-258

NOTICE OF PUBLIC HEARING PUBLIC COMMENTS.
Hello, My Name, is [redacted] and I am a member of the New Mexico Medical Cannabis Program and Patient Advocate Alliance.

TOP Priority OPEN up "micro business" licenses immediately in preparation to compensate for Rec use is implemented. Allow small family farms and entrepreneurs to enter the market to be able to sell to LNPPs for Medical/Rec use, allow Micros to sell directly to medical patients who have specific needs.

- Allow 3rd party business to test, process and package for a patients to have their medication administered as specifically needed: e.g. Tinctures, FECO, Topicals, extractions as well and edible manufacturing carts ECT.....
- Include program funded grows for veterans and a system set up for low cost meds for those in poverty on fixed income and no ability to afford adequate medication.

Consumption areas for qualified patients, Should NOT be Limited to LNPP sites that are operated by any business to participate by approval of an application to be anywhere and everywhere. Near military bases, reservations, and near borderlines. PATIENTS NEED THIS!

Example: Tattoo shops to offer a dab for pain control, Huka Lounges, Hotels, Bud and Breakfast, cafes or coffee shops and restaurants with infused cuisine menu.

"Cannabis testing to include also mold, heavy metals and to have a Member of the DOH to cut the samples from bottom, middle and tops. [redacted]

Written public comment may also be submitted prior to the date of the hearing. Please submit any written comments regarding the proposed rule amendments to the attention of:
Andrea Sundberg
NM Department of Health
Medical Cannabis Program
P.O. Box 26110
Santa Fe, NM 87502-6110
Or at:
MCP.comment@state.nm.us

2019-2-39

Reynold Greenleaf & Associates, LLC

New Mexico Department of Health
Medical Cannabis Program
ATTN: Andrea Sundberg
PO Box 26110
Santa Fe, NM 87502
Submitted via email to MCP.comment@state.nm.us
CC: MCP Director Dominick Zurlo, DOH Secretary Kathyleen Kunkel

January 10, 2020

My name is William Ford, and I am the Managing Partner at Reynold Greenleaf and Associates (RGA). Thank you for accepting our comments today regarding the future of our Medical Cannabis Program (MCP). These concerns represent a comparatively small number of the overall proposed changes but could have disproportionate consequences to the Program. RGA is grateful to the Department and the Administration for taking action to make the Program better and more accessible for patients. We appreciate you accepting our comments and hope that we can be more involved in the process moving forward.

RGA's first concern is that the Department of Health recognize that the costs associated with testing are all but certain to be passed onto patients. Because of this reality, it is extremely important that the MCP consider the necessity and the efficacy of each of these new rules and testing requirements. The MCP has a responsibility to execute due diligence in assessing each of these tests and their importance in contrast to their cost and consequence. As well, the MCP should be working closely with all stakeholders — including LNNP's, testing labs, manufacturers, patients, advocacy groups, etc. — to determine the best course of action. Only then, should the MCP move forward to regulate and require any new testing parameters.

We at RGA share the view with the Department of Health that there is a clear and present need for good regulation, progressive rulemaking, and consistent oversight of the Medical Cannabis Program. We feel strongly that nothing is more important than protection of the patient consumer. As well, safe access and affordability should be major considerations. RGA recommends that the MCP begin to focus on enforcement of existing rules and regulations surrounding quality, labeling, packaging and current testing parameters. Although we appreciate the intention of the MCP in proposing new rules, we feel compelled to mention an obvious absence of relevant data, evidence-based rationale, and enforcement considerations for many of these new proposed rules. There is no sense in adding new rules if there is no current enforcement of existing rules.

RGA agrees with many positions and recommendations of the Cannabis Chamber of Commerce that the proposed changes to testing regiments are largely unnecessary, excessive, and cost prohibitive to patients. The new requirements and increase in cost may, in fact, have the unintended consequence of forcing patients towards the illicit market. Estimates reach nearly $4 million annually in new testing costs to LNPP's and manufacturers, with an estimated increase in price of an additional $5-$8 per gram in some cases, resulting in a nearly 100% price increase to patients on the retail side.

RGA would strongly recommended that the requirements for the same testing on manufactured products where there is no potential for a different result from previous testing on dried usable

Reynold Greenleaf & Associates, LLC

cannabis be removed. This is a redundancy which would serve no purpose except to increase costs to patients.

Additionally, RGA stands with many arguments made by Kathleen O'Dea of Scepter Labs and would request the Department reconsider their inclusion of Mycotoxin testing, Heavy Metals testing and take a second look at the overall viability of their testing requirements (many of the tests require a tolerance or calibration level or a licensing qualification that may be unattainable.) In terms of routine Mycotoxin testing, RGA refers to data produced by Ms. O'Dea, which shows testing fees of over $700,000 without registering a single positive result. In fact, to RGA's knowledge, there has never been a positive mycotoxin test in the history of New Mexico's Medical Cannabis Program.

RGA recommends letting data, market leaders, and professional scientists make evidence-based recommendations. We echo previously submitted evidence-based recommendations from other institutions and scientists such as Ms. O'Dea (Scepter Labs), Mr. John Christopher Romero, (RGA), Dr. Barry Dungens (Rio Grande Analytics); and their professional opinions as to what is and is not appropriate and safe for patients to interact with.

RGA also shares the goal of making product information readily available to patients and keeping the general public safe with clear labels indicating THC content. Had RGA been consulted regarding this objective, we would have recommended that these requirements are unrealistic in terms of available space on many cannabis products, for instance, the amount of information included in Table 8 is not possible to include on smaller containers at 8-point font or larger. RGA additionally would have agreed with the Cannabis Chamber that the information on the proposed label and Drug Information Sheet is largely duplicative and wasteful. RGA would recommend simply that the materials information and product warnings be available to patients on request only, or through either pre-printed sheets available at point of purchase or online through web sites.

RGA recommends against making rules without meaningful input from industry stakeholders, just for the sake of rulemaking, with no plan for enforcement or implementation. RGA alternatively would request an increase in funding for the enforcement arm of the division so that frequent and rigorous inspections can begin. We would welcome an increase in site visits from the Department regarding enforcement of current rules and regulations for all farms, dispensaries, and manufacturing sites. At the time of this meeting, the enforcement division of the DOH doesn't have the manpower to properly inspect, investigate, and regulate in accordance with the current rules and regulations of the Lynn and Erin Compassionate Use Act. If enacted, these additional rules are only setting the program up for future, and possibly imminent, failure.

Thank you for your time.

William Ford
Managing Director
Reynold Greenleaf & Associates

2019-2-4V

[redacted]

NM Department of Health
Medical Cannabis Program
1474 Rodeo Rd., Suite 200
Santa Fe, NM 87505
505-827-2321

To Whom It May Concern:

My name is [redacted] and I have been a patient enrolled in the NM Medical Cannabis Program since 2013. I have been advocating for patients since 2013 and was a participant the SB 105 Memorial Task Force on Affordability and Accessibility, created by Sen. Ortiz y Pinó in 2018.

I have been pushing for better testing requirements for medical cannabis products for many years and I'm pleased that the NM MCP is finally taking patient health more seriously. However, the rules do seem to be a bit overzealous and I wish more time be put into the formation of these new rules instead of mixing up what has been promulgated in other states.

Most patients really want to see new rules imposed for testing cannabis products for pesticides, molds and heavy metals, and I'm no different. But I am concerned with the high cost of this testing being passed on to patients, especially those who can barely afford this medicine now, never mind when prices increase as they most certainly will.

I suggest that if the yearly cost of licensing producers is decreased proportionately to the high cost of this new testing, this cost will not get passed on to the patients. This wouldn't be hard to figure out and would be an equitable solution. This would definitely show that the MCP has patient's best interests at heart.

As an employee of one of the newer Licensed Cannabis Producers I got to see first hand how the costs of things like testing impact the opening of a new cannabis business. The previous license holders had quite a few years to establish themselves with no testing requirements at all. With the newly proposed testing rules any new licenses issued in the future will have an extremely difficult time unless they come in very heavily invested, which will only promote larger corporations to descend on our medical cannabis program and eliminate the future option of small, craft cannabis businesses, which are much needed entities that can fill the voids of affordable cannabis products in our program.

Thank you for this opportunity to express my views.

[redacted]

[redacted]

2019-241

Hello My Name is [redacted] I am board member Advocate Alliance and a rural medical cannabis patient of almost 7 years now. Been coming to these meeting for a while hoping for some type of positive change maybe this year. I like to talk about testing 1st no amount of testing will make our medicine safe unless you make some rules for sample taking procedures. I can;t tell you countless times of Microwave or Ozone Sample stories I have heard from many employees of LNPP . Even times been to lnpp grows seen the machines with my own eyes. So to fix it maybe have DOH staff take samples in sealed custody bags to the lap. Do a full spectrum test this will be cost effective simple way to have consistent testing for our state cannabis. We all win.

I like ask you to remove the 2 personal production per address that discriminates against medical cannabis patients to the right of there plants. I know you let LNPP or Management company's grow multiple plant counts together. Purlife & MJ Espresso UH&GG R green leaf& Med zen just to name a few off the top of my head. So please let us MCP have our rights back to our plants this is our program. We jump thur hoops already even forced to tell landlords we are medical cannabis patients when we don;t own our home to get to grow this is a equality issues also. We have the rules open lets make some positive changes.

I would like to ask DOH to open up license. I watched LNPP bully Mcp with prices and quality Example was lucky to help have prices drops after conversation with the owner of PVP when he called me after I left a bad google review so ask why was Carlsbad 15 a gram and Roswell was 12 a gram same strain he said he didn;t know and would change it was glad to help but then just this week again after a live review of medicines that I had to eat a cracker to get the taste out of my mouth, they dropped it from 14 a gram to 10. So a second time in a year seen this company bully patients with prices and quality this happens everyday so unless we get some competition in our program you will help these greedy company make money off the sick you all know and seen the reports the Avg cost of our medicine has gone up after yall gave them more plants. It went down when yall gave us more license so please help all the people that are not here that are scared to speak for this change. Thank you.

Patricia monaghan

MIAMI New Times

Two Bills Could Dismantle Florida's Medical Marijuana "Cartel"

ALEC ANELLO | NOVEMBER 22, 2019

In Florida, companies such as Philip Morris and Bacardi aren't required to cultivate and process raw plant material and then package, distribute, and sell their cigarettes and rum. But for some reason, state law requires medical marijuana producers to operate exactly that way.

Florida legislation requires the medical marijuana industry to be vertically integrated, meaning facilities that dispense medical marijuana on a retail level also must cultivate, process, and transport their product. Florida Gov. Ron DeSantis himself has likened vertical integration to a "cartel." In July, a Tallahassee appellate court issued a ruling saying the system is unconstitutional. The issue will next be heard by the Florida Supreme Court.

But if the courts don't dismantle the system soon, lawmakers might do it first. In recent weeks, two bills have been added to Florida's rapidly growing roster of marijuana-based legislation in an attempt to make the industry function more efficiently.

In the Senate, Democratic state Sen. Perry Thurston has introduced SB 212, which would place restrictions on Florida's monopolistic practices and encourage diversity within the industry. Essentially, the bill prohibits retail facilities from producing their own products, as they are currently required to do. The hope is that by prohibiting physicians and caregivers from having economic interests in retail facilities, they

would have no incentive to improperly prescribe or administer marijuana as medication.

The bill further seeks to curtail the vertical integration of the market by limiting the number of medical marijuana treatment centers with whom a retail facility can be associated and disallowing treatment centers from owning or operating dispensaries.

Thurston's bill would also prohibit applicants listed as an owner, board member, officer, or manager from being listed on more than one licensure application for medical marijuana retail facilities. Finally, SB 212 would identify applicants with strong diversity plans and implement educational programs to help them obtain licensure. This bill would enable the state to begin licensing treatment centers in August 2020.

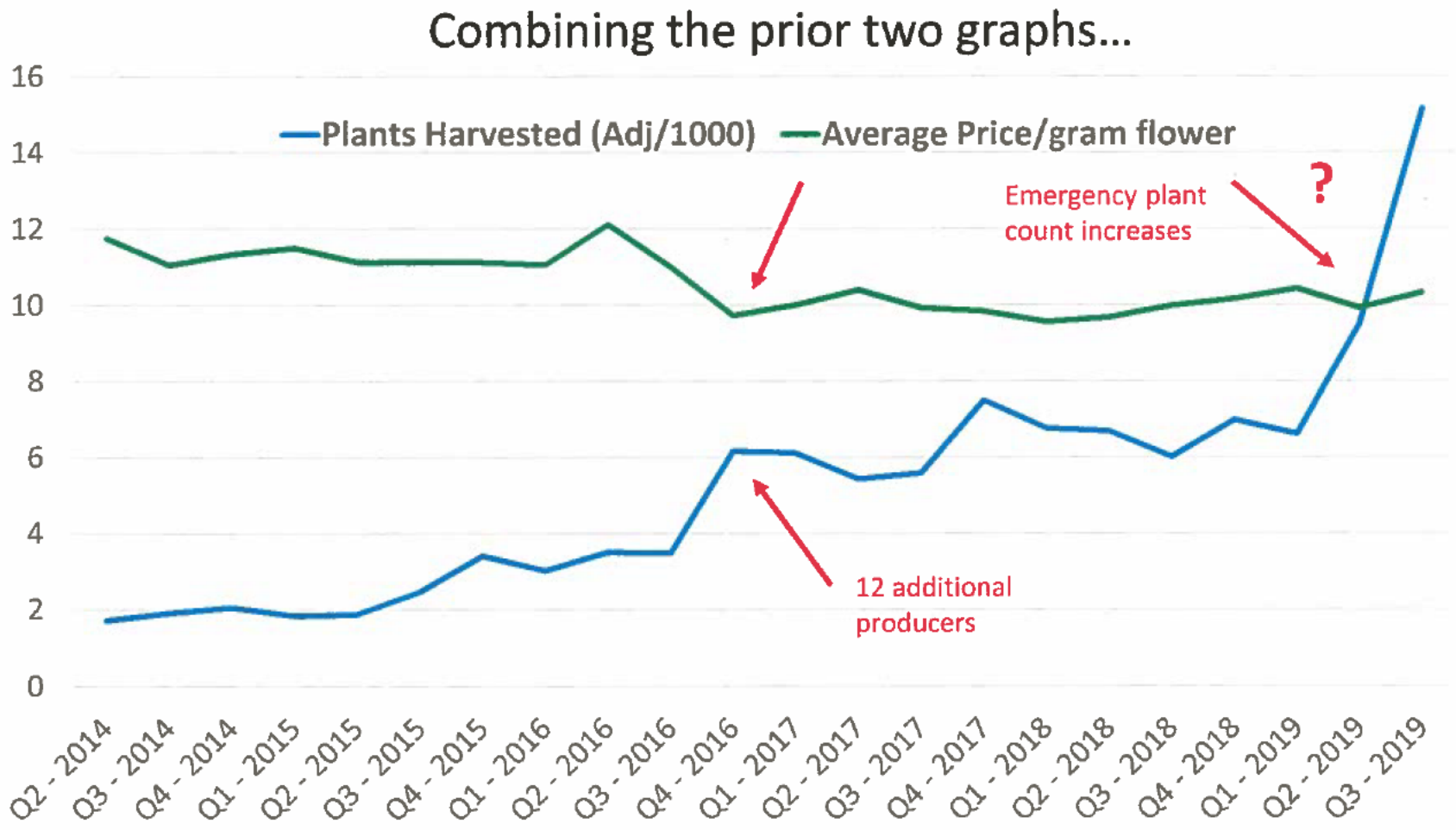
The second bill, HB 149, has been introduced by Republican state Rep. Anthony Sabatini. It would require entities that "cultivate, process, transport, or dispense marijuana" to be licensed as medical marijuana treatment centers. The changing of the language from "and" to "or" indicates the same company does not need to plant marijuana, distribute it, and do everything in between. This bill would remove the current limits on the number of applicants allowed to be approved within a specific timeframe and geographic area.

Notably, HB 149 states that preference must be given to minority farmers and companies that currently process, concentrate, and can citrus fruits. Because of citrus greening and urbanization, Florida's citrus industry — a longtime staple of agriculture and a dependable source of income for farmers — has been steadily declining. The Sunshine State has a long history of supporting its citrus farmers, and Sabatini's bill intends to continue that tradition and pave the way for processors to transition into the burgeoning marijuana industry. Writing legislation that prioritizes minority farmers and local companies indicates the movement to make Florida's medical marijuana environment more inclusionary is growing.

HB 149 would also require a performance bond of $5 million for each applicant, or $2 million if the applicant serves 1,000 or more patients. Issuing performance bonds is a double-edged sword, though: The process verifies that each applicant has the proper financial requirements, but it would come at a high cost to startups, thereby shutting out a large number of mom-and-pop and boutique operations.

However, the current vertical integration model makes entering the industry difficult for small companies by creating a high monetary barrier. And by requiring companies to cultivate, process, distribute, and retail their products, the law prevents any one company from specializing in and excelling at a specific aspect. In turn, Florida's medical marijuana industry operates at a suboptimal level, wasting time and money and resulting in artificially high retail prices.

https://www.miaminewtimes.com/content/printView/11319276


Combining the prior two graphs…
16
14
12
10
8
6
4
2
0
Plants Harvested (Adj/1000)
Average Price/gram flower
Emergency plant count increases
?
12 additional producers
Q2 - 2014
Q3 - 2014
Q4 - 2014
Q1 - 2015
Q2 - 2015
Q3 - 2015
Q4 - 2015
Q1 - 2016
Q2 - 2016
Q3 - 2016
Q4 - 2016
Q1 - 2017
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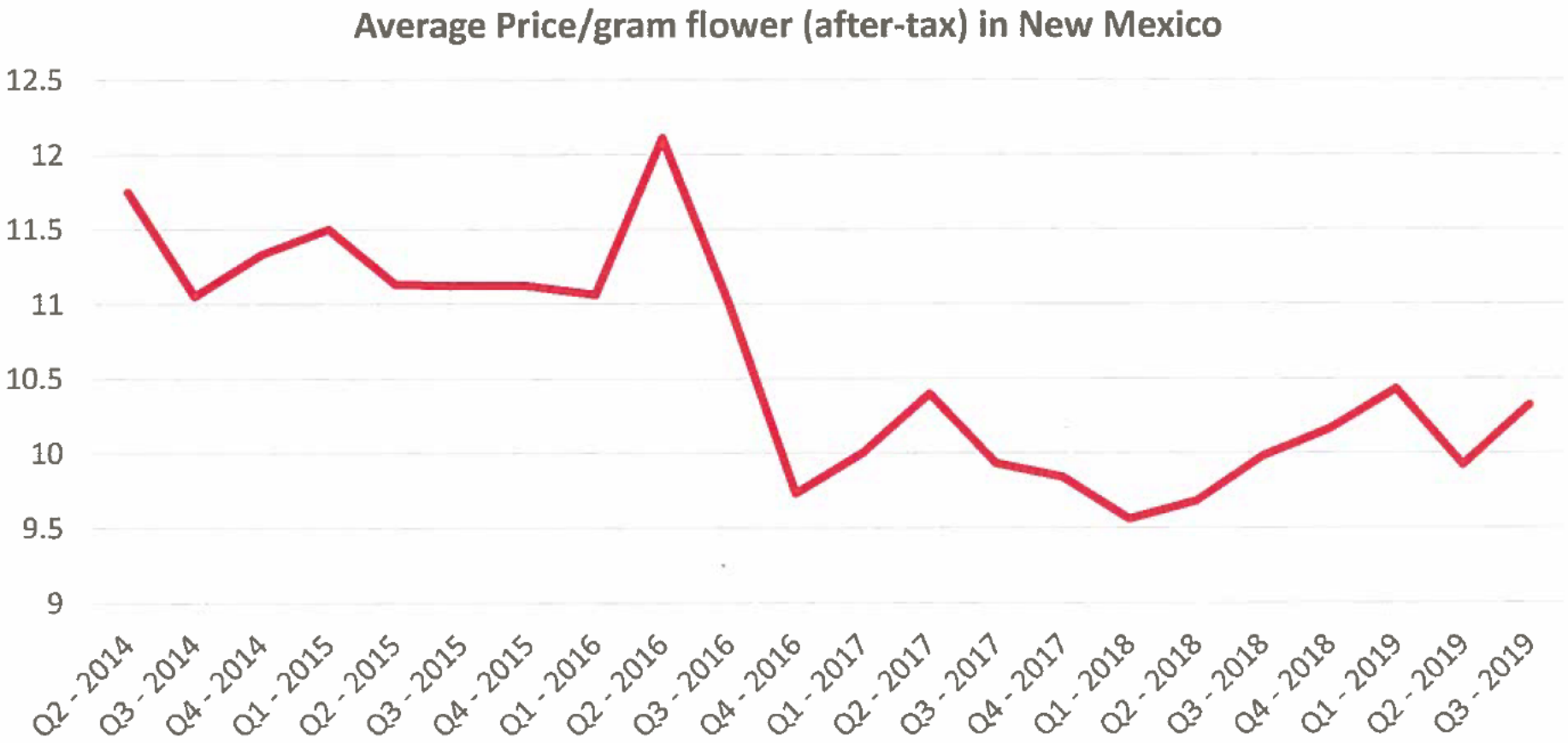
Q1 - 2018
Q2 - 2018
Q3 - 2018
Q4 - 2018
Q1 - 2019
Q2 - 2019
Q3 - 2019


Average Price/gram flower (after-tax) in New Mexico
12.5
12
11.5
11
10.5
10
9.5
9
Q2 - 2014
Q3 - 2014
Q4 - 2014
Q1 - 2015
Q2 - 2015
Q3 - 2015
Q4 - 2015
Q1 - 2016
Q2 - 2016
Q3 - 2016
Q4 - 2016
Q1 - 2017
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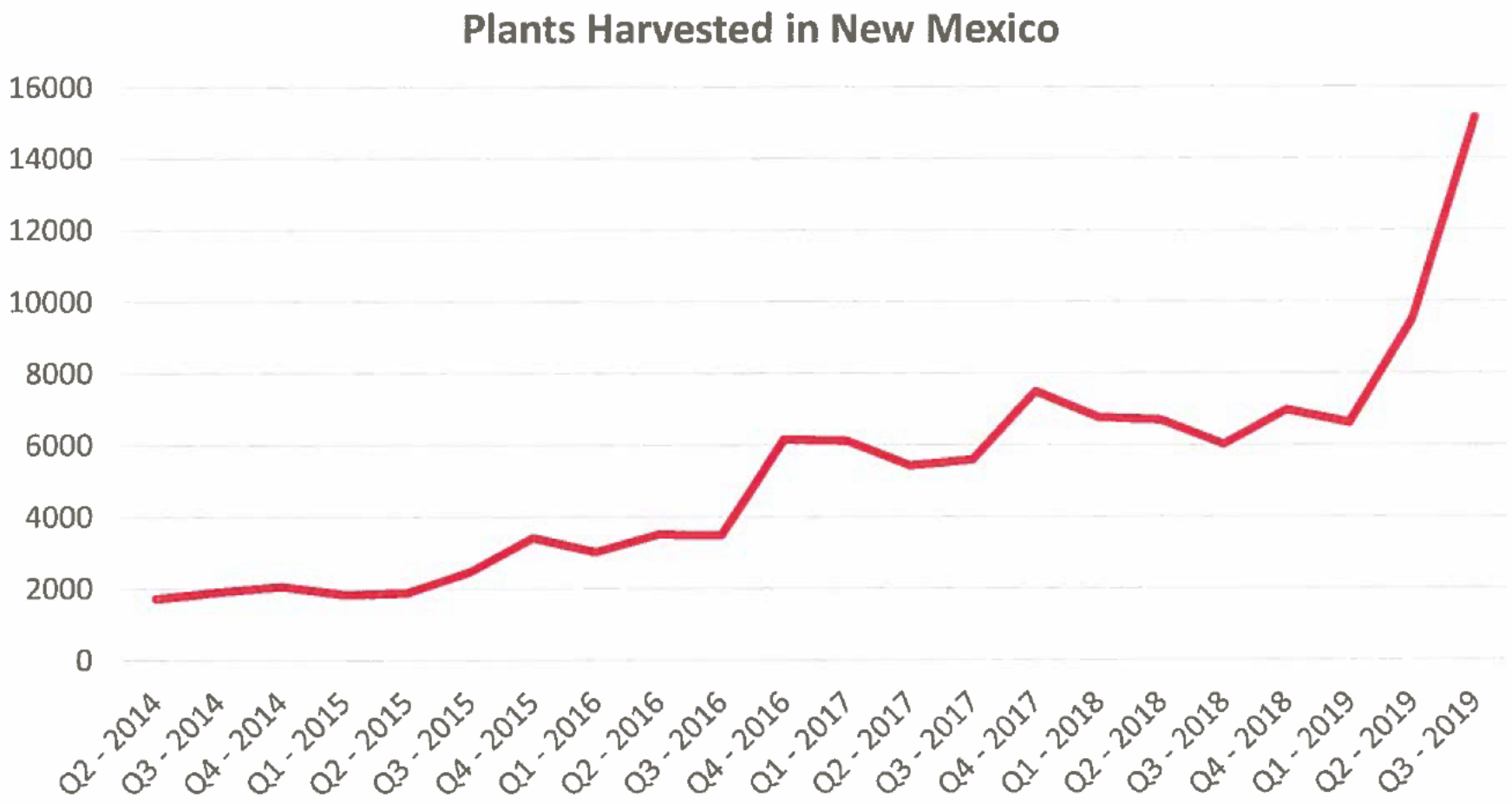
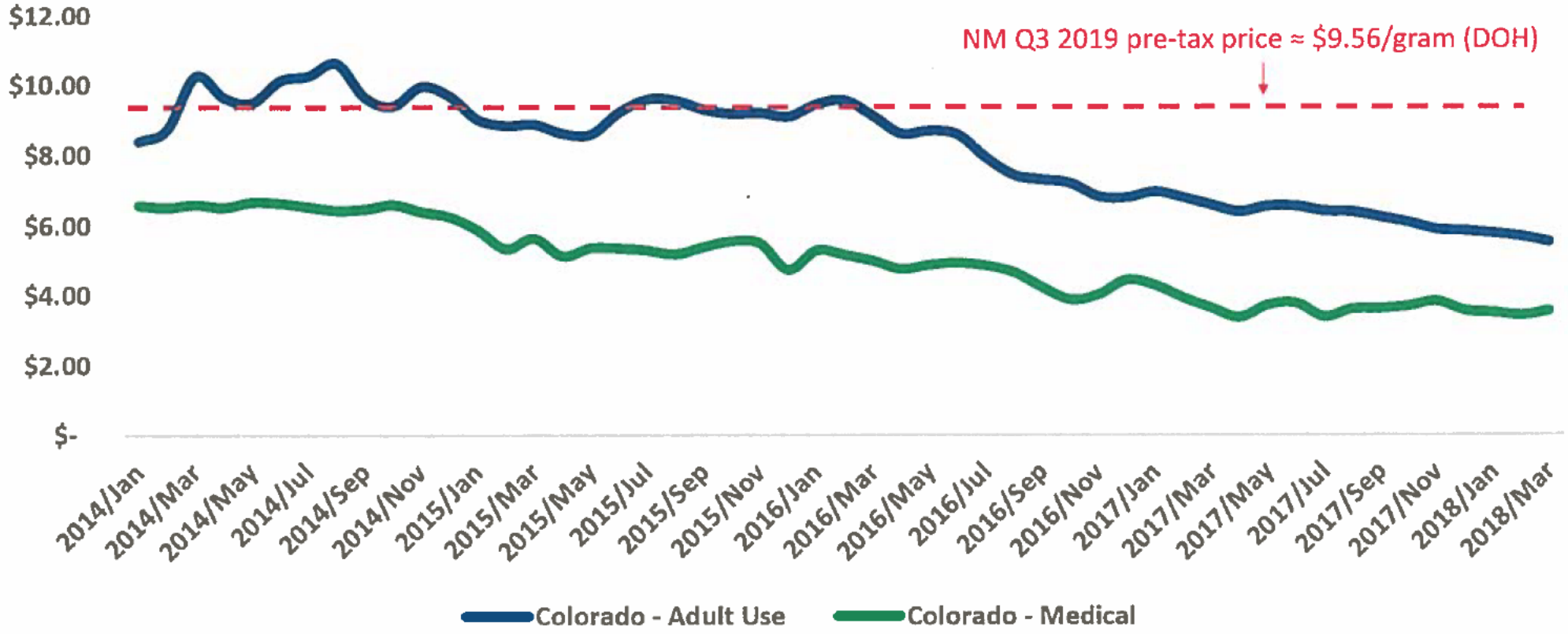
Q2 - 2018
Q3 - 2018
Q4 - 2018
Q1 - 2019
Q2 - 2019
Q3 - 2019


Plants Harvested in New Mexico
16000
14000
12000
10000
8000
6000
4000
2000
0
Q2 - 2014
Q3 - 2014
Q4 - 2014
Q1 - 2015
Q2 - 2015
Q3 - 2015
Q4 - 2015
Q1 - 2016
Q2 - 2016
Q3 - 2016
Q4 - 2016
Q1 - 2017
Q2 - 2017
Q3 - 2017
Q4 - 2017
Q1 - 2018
Q2 - 2018
Q3 - 2018
Q4 - 2018
Q1 - 2019
Q2 - 2019
Q3 - 2019

COLORADO

Average Retail Price Per Gram (Pre-Tax)



https://images.potguide.com/blog/05-16-18/avg-retail-ppg-full.png

Description

- Data on plants harvested and average price per gram of flower come from the New Mexico Department of Health's website
- Colorado average price per gram image comes from https://images.potguide.com/blog/05-16-18/avg-retail-ppg-full.png

Sarah S. Stith, Assistant Professor of Economics

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Albuquerque, NM 87131

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Dear LNPP's, Manufacturers and Customers,

As you know the DOH has proposed a revised set of rules that will have great impact on how we do business. The proposed rules mandate larger sample sizes, new tests and expensive new equipment, new equipment for existing tests and more stringent passing levels.

Because my comments are lengthy and cannot be made in the three minutes allowed, I thought I would send them to you ahead of the hearing.

As your testing laboratory, we are strongly opposed to many of these changes. We do not believe the rules will make medicine safer and may have a negative impact on patient safety as more and more patients seek less expensive medicine from the black market.

Our overarching concern is that much of the testing is unnecessary, expensive, not supported by empirical data and will not enhance or ensure patient safety. Even though other states may have imposed similar or identical regulations, they have done so without regard to any data supporting the necessity of such testing and have ignored scientific experts. Merely copying another state is not adequate justification for making new rules here. Furthermore, New Mexico produces a limited amount of cannabis due to the limited number of growers and plant limits. This makes the cost of testing significantly higher per unit of cannabis than in other states. There is no rational, nor scientific, basis for imposing heavy metal testing, mycotoxin testing or total yeast and mold testing. Heavy metals are seen in 0.11% and mycotoxins at 0.4% of the samples nationally and are likely false positive results. New Mexico producers have paid Scepter over $704,205.00 to test 15,649 samples for mycotoxins without finding a single positive result. Cannabis plant material will not support the formation of mycotoxins. It is a scientific fact. Period. There is no rational basis for requiring this test. Likewise, heavy metals, except the price tag will be much, much higher. Cannabis grown indoors in artificial media will not produce heavy metals.

Whether other states impose such requirements should not be the benchmark. Good science and empirical data should.

The following proposed requirements will create a significant negative impact on the medical cannabis program and will affect the cost of patient medicine while doing nothing to improve the safety of patient medicine:

The following are new tests proposed by the DOH: Pesticides, Heavy Metals, Moisture content, Coliforms, and potency testing for extracts <30% THC, supplements, teas, edibles, decoctions, infusions, tinctures, kief/rosin. In addition, the DOH will require HPLC testing for mycotoxins.

Pesticides and Heavy Metals
Pesticides and heavy metal testing will require that the labs re-tool and acquire new instrumentation. The estimated cost for each testing platform is approximately $250,000 for a total of $500,000. These instruments can be financed but the monthly cost will be approximately $30,000 for each one. The cost to perform each test will be $300-$350 per sample and will add $600-700 to the current price of a full panel test. Full panel testing will increase from $150 to a minimum of $750. The proposed rules require testing flower and concentrates. Accordingly, the testing cost of any product batch that is manufactured from a cannabis derived concentrate will be a minimum of $1,500 even if post-product testing is not required.

Heavy Metals
Heavy metal testing is not necessary for indoor grown cannabis. The Cannabis Safety Institute recommends heavy metal testing ONLY for cannabis grown on farmland with a historical use of arsenic based pesticides. IT IS IMPOSSIBLE FOR CANNABIS GROWN IN ARTIFICIAL SOIL TO TEST POSITIVE FOR HEAVY

METALS. Out of 70,000 cannabis samples tested for heavy metals nationwide and reported to the Confident Cannabis database, only 0.11% tested positive for heavy metals and these were from plants grown outdoors.

Mycotoxins

The production of mycotoxins requires fats or lipids that are not present in cannabis flower. Testing for mycotoxins should not be required.

Notwithstanding *never* seeing a single mycotoxin failure because cannabis inflorescences cannot support the formation of mycotoxins, the Department of Health is proposing to require a more sensitive test for mycotoxins in the future. In fact, the Department of Health is proposing HPLC testing to *quantify each mycotoxin individually*. Quantifying each mycotoxin individually is completely unnecessary because the passing standard requires a combined total. Most reasonably priced mycotoxin test kits utilize combined totals. The new standard will require the acquisition of new equipment which will add 10% to the price of an existing mycotoxin panel.

Microbial Testing

Under the proposed rules, microbial testing will be required for six new categories of products. None of these product categories should require full microbial testing according to the Cannabis Safety Institute. The only product category that should be tested is fresh raw cannabis.

Edibles and Ingestibles

According to the Cannabis Safety Institute white paper, "Cannabis food products are as likely to become contaminated as any other processed or prepared commercial food product. But because of its unique attributes, *Cannabis is the least likely component to be the source of contamination in any food product*. Cannabis is present in foods as an extract of the plant material. This plant material is dried to a safe level before extraction. And then either during or after extraction it is usually subject to a decarboxylation process that serves as a heat-kill step. The vast majority of the extraction processes are themselves sterilizing."

Coliforms

Coliform testing has not been required thus far but our lab has been testing for coliforms since 2014. We have done over 70,000 coliform tests along with our E.coli test. The proposed rules will require that total coliforms be reported and have set a very difficult passing rate. We estimate that 25% of all samples will fail the new coliform standard. The DOH should adopt a passing rate in keeping with other states.

Total Yeast & Mold

The Cannabis Safety Institute does **not** recommend testing for total yeast and mold. This test can culture only a small percentage of fungal species and only provides general quality information. If the test is used, they recommend a standard of 10,000 cfu/gram or 100,000 cfu/gram. New Mexico requires 1,000 cfu/gram and is way out of step with other states on this standard. They do recommend testing for Aspergillus spp. which can cause invasive pulmonary aspergillosis and state that they are the only pathogens that represent a clear and certain danger on cannabis.

Sample sizes

The increase in the proposed sample sizes are largely due to microbial testing. The DOH proposes to require 10 gram samples for both salmonella/e.coli testing and 10 gram samples for the other tests. We assume this is based upon recommendations from the State Scientific Laboratory. We do not believe these

recommendations are well-founded after reviewing the State Lab's validation report where they tested 27 cannabis samples and attempted to validate a method for the microbial testing of cannabis.

The State Lab had difficulty developing a method for testing cannabis and essentially killed the organisms by placing large samples in small volumes of nutrient solutions. We do not think that their difficulties should give rise to a new law imposing new procedures on labs who do not have difficulty doing microbial tests. If anything, the State Lab should recognize that attempting to utilize a larger than necessary sample size can give rise to difficulties in testing.

We commissioned a full validation study (from NMSU in 2018) of our methods for both salmonella and E.coli utilizing 1 gram samples. We have performed over 70,000 microbials utilizing these methods without difficulty and successfully pass our third party proficiency test each year.

Cannabis plants yield approximately 250 grams to 700 grams per plant. We do not believe that increasing the sample size from 1 gram to 10 grams will significantly increase the liklihood of finding the microbial needle in the haystack but will cost more and will impact producers and patients.

Please attend the public hearing on the 16th.

Thank you for your loyal business. We appreciate you.

Kathleen for Scepter

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