

November 9, 2021

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

Re: Comments on Proposed Rule 7.34.3

Dear Department of Health,

Please accept these public comments from New Mexico Top Organics-Ultra Health, Inc., and Ultra Health, LLC sent in relation to the proposed Department of Health ("DOH") regulation 7.34.3 NMAC, to be considered ahead of the November 12, 2021 public hearing.

I. Adequate Supply Purchase Limitation

The proposed rule 7.34.3.9 NMAC states, "A qualified patient and a qualified patient's primary caregiver may collectively purchase within any three-month period a quantity of usable cannabis no greater than 425 total units. For purposes of department rules, this quantity is deemed an adequate supply...A qualified patient and a primary caregiver may possess the amounts of cannabis permitted in accordance with the Cannabis Regulation Act, NMSA 1978, § 26-2C-1 et seq. Once commercial cannabis sales are authorized by the Cannabis Control Division to begin in accordance with NMSA 1978, § 26-2C-6(K), qualified patients and primary caregivers will be able to make commercial purchases above the adequate supply limit, in accordance with the Cannabis Regulation Act."

This proposed regulation is illegal. It violates the Cannabis Regulation Act in multiple ways.

First, the Cannabis Regulation Act ("CRA") transferred the vast majority of the medical cannabis program from DOH to the Cannabis Control Division ("CCD") within the Regulation and Licensing Department ("RLD"): "Except for administration of the medical cannabis registry, the power, duty and authority of the department of health related to the medical cannabis program shall be transferred to the division on the effective date of the Cannabis Regulation Act." NMSA 1978, § 26-2C-5 (2021).

Thus, DOH legally has no authority to limit purchases for medical patients in any way. DOH has no authority to promulgate any rules related to cannabis, except if those rules concern the medical cannabis registry. DOH simply has no legal authority or power to promulgate or enforce its proposed rule 7.34.3.9 NMAC.

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Indeed, the "medical cannabis registry" is defined in the Cannabis Regulation Act as the "system by which the department approves or denies applications and issues and renews registry identification cards for qualified patients." § 26-2C-3(MM). Limiting the purchases of medical cannabis patients, which is what 7.34.3.9 NMAC does, has nothing to do with processing registry identification cards.

Therefore, on June 29, 2021 (the effective date of the Cannabis Regulation Act), DOH lost any authority that would allow it to define an adequate supply, create purchase limitations, or enforce purchase limitations.

Second, Section 26-2C-25(A)(1) of the CRA provides that the "following conduct is lawful for a person who is twenty-one years of age or older and shall not constitute grounds for detention, search or arrest of a person...possessing, using, being under the influence of, displaying, **purchasing, obtaining** or transporting **not more cannabis than authorized by the Cannabis Regulation Act** or the medical cannabis program" (emphasis added). There is no specific effective date for this section, and so the effective date was June 29, 2021, which is the generally effective date of the CRA.

There are several coordinating sections of the CRA that further clarify the extent of the rights granted by Section 26-2C-25(A)(1). Section 26-2B-25(A)(2) of the CRA provides that the "following conduct is lawful for a person who is twenty-one years of age or older and shall not constitute grounds for detention, search or arrest of a person ...possessing in excess of two ounces of cannabis, sixteen grams of cannabis extract and eight hundred milligrams of edible cannabis if the excess is stored in the person's private residence and not visible from a public place." Section 26-2C-3(B)(4)(a) directs the Cannabis Control Division within RLD to promulgate rules stating that "a person who is twenty-one years old or older shall not purchase more than two ounces of cannabis, sixteen grams of cannabis extract and eight hundred milligrams of edible cannabis at one time" (emphasis added).

All of these sections broadly refer to a "person"—not a "consumer," not a "recreational purchaser," and not a "non-medical purchaser." "Person" plainly includes medical cannabis patients. Furthermore, Section 26-2C-25(A)(1) specifically includes "possessing," "purchasing" and "obtaining." It is both a possession limitation and a purchase limitation.

Section 26-2C-25(A)(1) specifically allows "persons" to purchase "not more cannabis than authorized by the Cannabis Regulation Act **or** the medical cannabis program," without reference to whether the higher or lower amount controls. Thus, if the person purchased the higher amount, it would still be lawful.

When read in the context of 26-2C-3(B)(4)(a) and Section 26-2C-25(A)(2), Section 25(A)(1) of the CRA specifically and clearly allows any "person" twenty-one years of age or older to purchase, on and after June 29, 2021, "not more cannabis than authorized by the Cannabis Regulation Act." The amount of cannabis authorized for purchase "at one time" is two ounces of cannabis, sixteen grams of cannabis extract and eight hundred milligrams of edible cannabis. DOH's proposed 7.34.3.9 NMAC, which would allow a qualified medical cannabis patient to purchase only 450-grams-over-90-days, blatantly contradicts the statutory provision.

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In a broader sense, the "adequate supply" provisions—both statutory and regulatory—of the Lynn and Erin Compassionate Use Act have been nullified by the enactment of the Cannabis Regulation Act.

Under the Compassionate Use Act, possessing and purchasing cannabis was only lawful for qualified medical patients, and the purchases were only lawful up to a certain volume set by regulation. Under the Cannabis Regulation Act, possessing and purchasing cannabis became lawful for all adults beginning on June 29, 2021, and it became lawful up to a volume defined in statute, rather than a volume set by regulation.

The CRA's intent to displace DOH's authority over patient purchase limitations is obvious from the CRA's text. First, Section 26-2C-5 clearly states, "Except for administration of the medical cannabis registry, the power, duty and authority of the department of health related to the medical cannabis program shall be transferred to the division on the effective date of the Cannabis Regulation Act." By severely limiting DOH's authority, the CRA indicates its intent to supplant and supersede DOH's arbitrary and capricious limitations on medical patient purchases.

Next, Section 70 of the CRA, which is titled "temporary provision," reads, "To the extent any administrative rules are inconsistent with the provisions of this act, such rules are null and void." The provisions of the Act, as reviewed above, unmistakably authorize "persons" to purchase not more than two ounces of cannabis, sixteen grams of cannabis extract and eight hundred milligrams of edible cannabis at one time, and that provision went into effect on June 29, 2021. There is nothing in the CRA that limits its effectuation to certain dates.

As between statutes and regulations, statutes trump regulations: any agency action "that is not in accordance with law should be reversed if the agency unreasonably or unlawfully misinterprets or misapplies the law." *N.M. Mining Assn. v. N.M. Water Quality Control Comm.*, 2007-NMCA-010, ¶ 11, 141 N.M. 41, quoting *Archuleta v. Santa Fe Police Dep't*, 2005 NMSC-006, ¶ 18, 137 N.M. 161.

Furthermore, between two conflicting statutes, the later, more comprehensive one governs. "If statutes appear to conflict, they must be construed, if possible, to give effect to each. If the conflict is irreconcilable, the later-enacted statute governs." NMSA 1978, § 12-2A-10 (A) (1997). "If a statute is a comprehensive revision of the law on a subject, it prevails over previous statutes on the subject, whether or not the revision and the previous statutes conflict irreconcilably." § 12-2A-10 (C).

The Cannabis Regulation Act is a comprehensive revision of the law regarding cannabis, and therefore it prevails over the Compassionate Use Act where the two statutes conflict.

DOH's proposed rule is therefore illegal.

II. Additional Amounts of "Commercial" Cannabis

DOH's rule 7.34.3.9 NMAC states, "Once commercial cannabis sales are authorized by the Cannabis Control Division to begin in accordance with NMSA 1978, § 26-2C-6(K), qualified patients and primary caregivers will be able to make **commercial purchases** above the adequate supply limit, in accordance with the Cannabis Regulation Act" (emphasis added).

This provision is illegal. Now, although DOH's rule fails to define "commercial purchases" and fails to even define "commercial," it is obvious what DOH attempts to do here.

On September 24, 2021, DOH wrote, in an answer filed in case D-202-CV-2021-04058, "As commercial sales are not currently permitted, the LECUA [Compassionate Use Act] limits qualified patients to purchases of eight ounces within a three-month period. See 7.34.3.9(A), 7.34.4.8(L) NMAC. Hypothetically, if a qualified patient were able to purchase on the commercial, non-medical market above those limits currently permitted by regulation, by statute the cannabis excise tax would apply."

The meaning of DOH's proposed 7.34.3.9 NMAC is clear: medical cannabis patients may purchase 450-units-over-90-days without paying any applicable tax, but any volume exceeding the 450-units-over-90-days would be taxed.

There is no statutory justification for this position, and the proposed regulation violates statute. NMSA 1978, Section 7-42-3(C) (2021) states, "The cannabis excise tax shall not apply to retail sales of medical cannabis products sold to a qualified patient or a primary caregiver who presents a registry identification card issued pursuant to the Lynn and Erin Compassionate Use Act [Chapter 26, Article 2B NMSA 1978] or a reciprocal participant who presents similar proof from another state, the District of Columbia or a territory or commonwealth of the United States at the time of the sale."

Section 7-42-3(C) contains no volume limitation whatsoever. It simply says that "sales of medical cannabis" to "a qualified patient or a primary caregiver who presents a registry identification card" are not subject to the excise tax. By claiming that volumes of cannabis "above the adequate supply" limit are "commercial" and therefore taxable, DOH adds words to the statute. DOH has no authority to add words to the statute.

"An administrative agency has no power to create a rule or regulation that is not in harmony with its statutory authority." *Wilcox v. New Mexico Bd. of Acupuncture and Oriental Medicine*, 2012-NMCA-106, ¶ 7, quoting Rivas v. Bd. of Cosmetologists, 101 N.M. 592, 593, 686 P.2d 934, 935 (1984). "The administrative agency's discretion may not justify altering, modifying or extending the reach of a law created by the Legislature." *State ex rel. Taylor v. Johnson*, 1998-NMSC-015, ¶ 22, 961 P.2d 768.

Additionally, NMSA 1978, Section 7-9-73.2 (2021) states, "Receipts from the sale of prescription drugs and oxygen and oxygen services provided by a licensed medicare durable medical equipment provider and cannabis products that are sold in accordance with the Lynn and Erin Compassionate Use Act may be deducted from gross receipts and governmental gross

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receipts." Again, there is no volume limitation here. The only limitation on the gross receipts tax exemption is that the sale must be "in accordance" with the Compassionate Use Act, meaning that only qualified patients who present a registry identification card will be relieved from sales tax. However, the manner of sale does not imply any volume limitation. The DOH is once again reading words into the statute that are not there.

Finally, DOH has no authority to decide what is and what is not taxable. "Agencies are created by statute, and limited to the power and authority expressly granted or necessarily implied by those statutes." *Qwest Corp. v. N.M. Pub. Regulation Comm'n*, 2006–NMSC–042, ¶ 20, 140 N.M. 440, 143 P.3d 478. Nowhere in the Compassionate Use Act or DOH's enabling statute does the Legislature delegate the authority to DOH to make decisions on taxation. Taxation is an area of exclusive legislative control. In attempting to make decision on what should and should not be taxed, DOH is usurping the role of the elected Legislature.

The attempt by DOH to control taxation is recklessly unlawful. The statutes are obvious and clear, and DOH is simply crowning itself king. However, this is not a monarchy, and DOH is subject to standards of constitutionality. As an agency created by statute, it is limited to the power and authority defined by statute.

III. Reciprocal Limitations

DOH's proposed regulation 7.34.3.22(B) NMAC places the same purchase limitations on reciprocal participants as 7.34.3.9 NMAC places on medical cannabis patients. The purchase limitations are unlawful for the same reasons that 7.34.3.9 NMAC is unlawful.

IV. Lack of Substantial Evidence and Lack of Medical Advisory Board Consultation

Even *if* DOH had lawful authority to promulgate purchase limitations for patients (which it does not), the rule would still fail because it is unsupported by substantial evidence and because the DOH failed to consult the Medical Advisory Board.

It is axiomatic that all administrative regulations in New Mexico must be supported by substantial evidence. The DOH should know this based on the extensive briefings in case D-101-CV-2020-01485. The DOH has provided no evidence at all, let alone substantial evidence, to support its 425-units-over-90-days "adequate supply" figure. Attached is a screenshot of the Department's website where the rule is listed. There, the DOH has provided no studies, no surveys, no supporting documents, no comparisons to other states. In short, DOH has provided no evidence whatsoever.

Additionally, DOH has failed to consult with the Medical Cannabis Advisory Board. NMSA 1978, Section 26-2B-7 (2021) states, "After consultation with the advisory board, the department shall promulgate rules in accordance with the State Rules Act…" (emphasis added). Again, the Department should know of this requirement, since it was one of the reasons that a court overturned DOH rules in case D-101-CV-2020-01485. There is no indication that the DOH properly consulted with the Medical Cannabis Advisory Board.

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The last time the Medical Advisory Board met to discuss the "adequate supply" was in December 2020. However, any cannabis-related events that occurred prior to June 29, 2021 are irrelevant, because the world of cannabis in New Mexico fundamentally changed on June 29, 2021 with the effectuation of the Cannabis Regulation Act.

If DOH had consulted with the Board after June 29, 2021, the Board could have considered issues in light of the Cannabis Regulation Act, including the notion of simply setting the "adequate supply" to correspond with the statutory standard: "two ounces of cannabis, sixteen grams of cannabis extract and eight hundred milligrams of edible cannabis at one time." However, DOH failed to consult with the Board on this matter, which again renders the rule unlawful.

Sincerely,

<u>/s/ Kristina Caffrey</u> Kristina Caffrey Chief Legal Officer Ultra Health <u>kristina@ultrahealth.com</u> 505-401-7847 (cell)

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		Long Term	Care Dementia Training -	7.1.32 NMAC			
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	NMAC Proposed Rule 7.34.3						
	NMAC Proposed Rule 7.34.4.28						
	 NMAC Affidavit View Publication Public 7.34.2.7, 734.3, 734.4.28 						
 <u>NMAC Affidavit of Notice to the Public - NM Register 7.34.2.7, 7.34.3, 7.34.4.28</u> 							
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Certified Nurse-Midwives - 16.11.2							
	NMAC Summary of Purpose for Repeal and Replacement						
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			NMAC Proposed Rule 16	<u>5.11.2</u>			
	 NMAC Proposed Rule 16.11.2- Redlined for Comparison 						
	 NMAC Public Comments - Chris Mechels 9-18-20 						

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: Kristina Caffrey <kristina@ultrahealth.com>
Sent: Friday, November 12, 2021 1:33 PM
To: comment, MCP, DOH <MCP.Comment@state.nm.us>; Duke Rodriguez
<duke@ultrahealth.com>; Kylie Safa <kylie@ultrahealth.com>; Marissa Novel
<marissa@ultrahealth.com>
Subject: Re: [EXTERNAL] Public Comments on Proposed Rule 7.34.3

Good afternoon,

I have an addition to my comments. Today, New Mexico Top Organics-Ultra Health received the attached communication from the Department of Health regarding petitions made to the Medical Cannabis Advisory Board in years past. The Department of Health, in this communication, explains its decision to adopt the recommendation of the Medical Cannabis Advisory Board to increase the "adequate supply" amount.

This communication in no way changes the illegality of the DOH's proposal to adopt **any** adequate supply limitation. The Medical Cannabis Advisory Board recommended *in* **2020** that DOH should raise the patient purchase limit. Since that recommendation, the New Mexico legislature passed the Cannabis Regulation Act. Any cannabis-related events that occurred prior to June 29, 2021 are largely irrelevant, because the world of cannabis in New Mexico fundamentally changed on June 29, 2021 with the effectuation of the Cannabis Regulation Act. If DOH had consulted with the Board after June 29, 2021, the Board could have considered issues in light of the Cannabis Regulation Act. However, DOH failed to update the Board on its loss of statutory authority to set any "adequate supply."

More broadly, as explained in my previous comments, the Cannabis Regulation Act entirely eliminates DOH's authority to set *any* adequate supply. Therefore, it no longer matters what the Medical Cannabis Advisory Board thinks about adequate supply, because purchase limitations for all "persons"--which includes medical cannabis patients--are now set by statute.



MICHELLE LUJAN GRISHAM Governor

DAVID R. SCRASE, M.D. Acting Cabinet Secretary

Final Decision Regarding Medical Cannabis Advisory Board Reports and Recommendations

I. Decision

I have reviewed the recommendations of the Medical Cannabis Advisory Board contained in the following reports: November 16, 2020, December 9, 2020, and August 17, 2021. In accordance with Department rule 7.34.2.8(B) NMAC, the Medical Cannabis Advisory Board held public hearings on each of those days to review petitions from individuals requesting the addition of new medical conditions and medical treatments for inclusion in the list of debilitating conditions that qualify for the use of medical cannabis, proposed rule changes, and the quantity of cannabis that is necessary to constitute an adequate supply.

As part of my review, I have read the Advisory Board's recommendations and the materials submitted. Below is a summary of petitions and recommendations submitted to the Department of Health ("Department") with my final decision for each recommendation.

A. <u>Recommendation Regarding ADHD, ADD, Anxiety Disorder and Tourette's</u> <u>Syndrome</u>

The Medical Cannabis Advisory Board considered a petition to add ADHD/ADD, Anxiety Disorder and Tourette's Syndrome to the list of medical conditions qualifying for enrollment in the New Mexico Medical Cannabis Program. The Advisory Board recommended by a vote of 9-0, that ADHD/ADD, Anxiety Disorder and Tourette's Syndrome be included in the list of conditions qualifying for enrollment, but "only for adults".

ADHD/ADD was previously considered by the Department in 2015 and again in 2017. On both occasions, the Secretary of Health concluded that the potential adverse consequences of approving ADHD/ADD as a qualifying condition significantly outweighed the benefits. One trademark of ADHD/ADD is low levels of the neurotransmitter dopamine. Many medications used for treating ADHD/ADD work by increasing dopamine. Acute use of THC is also associated with an increase in dopamine release and is therefore thought to be of benefit in those with ADHD/ADD. Other than anecdotes, however, there is little clinical research to support these claims.

Also, over time, long term THC use is associated with an attenuated dopamine release and can result in a "blunting" of the dopamine system. This in turn may contribute to substance use behavior which might explain why people with ADHD are almost eight-times as likely to use cannabis compared to those who do not have ADHD. Studies also show that adults with ADHD are more than twice as likely to meet the criteria for Cannabis Use Disorder.

Anxiety was previously considered by the Department in 2017 and not adopted. The consumption of cannabis is known to generate anxiety, and if cannabis is used by someone who

already suffers from an anxiety disorder, it is possible that their condition will be exacerbated. The materials presented in the petition, while interesting, do not offer any assurance that this would not be the case.

A comprehensive review of human-based studies conducted by the National Academies of Sciences (NAS) published in 2017 observed that the NAS review committee did not identify any good-quality primary literature that reported on medical cannabis as an effective treatment for the improvement of anxiety symptoms. The report noted that there is limited evidence that CBD improves anxiety symptoms. It also stated that evidence from observation studies found moderate evidence that daily cannabis use is associated with increased anxiety symptoms and heavy cannabis use is associated with social phobia disorder.

Tourette's Syndrome was previously considered by NMDOH in 2017 and was not adopted to the list of qualifying conditions. There have been systematic reviews concerning the effects of cannabinoids (primarily THC) on Tourette's Syndrome that indicate low quality evidence to support the use of those substances to treat Tourette's syndrome. In terms of actual studies, it appears that there have been only a few small studies regarding the impact of THC on persons with Tourette's Syndrome, which suggested that consumption of THC could reduce vocal tics. However, methodological problems with those studies have been identified in some of the reviews. There have been no controlled studies on the effectiveness of medical cannabis itself in alleviating symptoms of Tourette's Syndrome. There are anecdotal reports that cannabis use may be of benefit. The evidence supporting the use of cannabis to address symptoms of Tourette's syndrome the use of low quality. This is reflected, for example, in the finding of the National Academy of Sciences in its 2017 report, in which it concluded that there is only "limited evidence that THC Capsules are an effective treatment for improving symptoms of Tourette's Syndrome."

In addition, adding a condition that is limited to "adults only" would create confusion and a problematic precedent. Many medical providers, parents, and minors may assume that since a condition was approved for an adult cohort, that cannabis may also be useful for the adolescent and pediatric populations. Given the sheer volume of children and minors that are diagnosed with ADHD/ADD, Anxiety Disorder, and Tourette's Syndrome, it is likely a large number of them, would be encouraged to begin cannabis use by a medical provider or parent unaware of the "adults only" distinction.

Finally, beginning in April 2022, adults older than 21 years of age with the above qualifying conditions will have the ability to access medical cannabis and see if it controls their symptoms without requiring a medical cannabis card. If the cannabis is successful in alleviating the symptoms of their condition, then the individual may continue using it on their own accord. Currently, however, there is insufficient data to support that cannabis is an effective treatment for these conditions and that its benefits outweigh the potential risks.

For each of the foregoing reasons, I decline to adopt the Advisory Board's recommendations to add ADHD, Anxiety Disorder, and Tourette's Syndrome to the list of medical conditions qualifying individuals for enrollment in the NM Medical Cannabis Program.

B. <u>Recommendation Regarding Tobacco Use Disorder, Hallucinogen Use Disorder and</u> <u>Stimulant Use Disorder</u>

The Medical Cannabis Advisory Board previously considered a petition to add Substance Use Disorder as a qualifying condition for enrollment in the Medical Cannabis Program in 2019. At that time, the recommendation was not adopted because the "umbrella" of Substance Use Disorder would include substances for which it is not clear that the risk/benefit profile of cannabis use is favorable for the health of the individual. The Medical Cannabis Advisory Board modified the current petition to only include Tobacco Use Disorder, Stimulant Use Disorder, and Opioid Use Disorder as Opioid Use Disorder was already a qualifying condition. Alcohol Use Disorder was also removed, in consideration that cannabis-only therapy without proper medical oversite could lead to significant morbidity and death. The Advisory Board voted 9-0 to recommend the addition of Tobacco Use Disorder, Hallucinogen Use Disorder and Stimulant Use Disorder to the list of qualifying conditions for enrollment in the Medical Cannabis Program.

Tobacco Use Disorder – There is very little clinical research to support the use of cannabis to alleviate tobacco usage. Furthermore, studies suggest that concurrent cannabis use was associated with decreased success with quitting smoking in patients seeking smoking cessation. Furthermore, despite downward trends in Cannabis Use Disorder (CUD) observed in the general population, CUD increased among cigarette smokers. Increasing trends in co-use rates have raised concerns that increased access to cannabis may reverse long-standing downward trends in tobacco use and increase the negative consequences associated with use of each substance. Simply substituting cannabis for tobacco is unlikely to result in tobacco cessation and poses unnecessary risk to patients, especially when there are better methods of smoking cessation.

Stimulant Use Disorder/Hallucinogen Use Disorder – Currently, no FDA-approved medications exist to treat Stimulant Use Disorder or Hallucinogen Use Disorder. Many of the practices to treat Stimulant Use Disorder and Hallucinogen Use Disorder (i.e., Cognitive Behavioral Therapy, Community Reinforcement Approach, Contingency Management, Motivation Interviewing) rely on inpatient and clinical settings with oversight. By adding these disorders to the list of qualifying conditions, patients may seek to resolve their addiction "at home" using cannabis instead of a clinical setting with proper medical oversight. These facts, coupled with the lack of significant clinical research to support the use of cannabis to treat these disorders, weigh in favor of denial of this petition.

Finally, beginning no later than April 1, 2022, adults older than 21 years of age with the above qualifying conditions will have the ability to access medical cannabis and see if it controls their symptoms without requiring a medical cannabis card. If the cannabis is successful in alleviating the symptoms of their condition, then the individual may continue using it on their own accord. Currently, however, there is insufficient data to support that cannabis is an effective treatment for any of these conditions and that its benefits outweigh the potential risks.

For each of the foregoing reasons, I decline to adopt the Advisory Board's recommendations to add Tobacco Use Disorder, Hallucinogen Use Disorder and Stimulant Use Disorder to the list of medical conditions qualifying individuals for enrollment in the NM Medical Cannabis Program.

C. <u>Recommendation Regarding an increase in the purchase limits of medical cannabis for</u> <u>qualified patients</u>

The Medical Cannabis Advisory Board considered a petition to increase the purchase limit recommended, by a vote of 8-1, that NMDOH increase the "adequate supply" three-month possession limit from the current 230 units standard to 420 units. Members of the MCAB expressed that the basis for this recommendation is their belief that a higher purchase limit would address the needs of patients that are applying for "unit increases" (under the medical exception identified in the current rule 7.34.3.9(C) NMAC. The Advisory Board further opined that the increase limit would require a higher supply, which in turn, may help to reduce cost and increase the variety of medical cannabis products and medicinal strains.

Recently, the Medical Cannabis Program has noticed an increase in the number of "unit increase" requests and recommends that the Department raise the patient purchase limit.

I am adopting the Advisory Board's recommendation that the "adequate supply" purchase limit be increased. In furtherance of this decision, the Department has proposed to amend Department rule 7.34.3.9 NMAC, to increase the adequate supply limit to 425 units (approximately 15 ounces) of dried cannabis material for a three-month period. The Department has also proposed to remove the "medical exception" at 7.34.3.9(C) NMAC in consideration of the fact that 425 units significantly exceeds the 345 units (230 + 115) that is currently allowed for persons with medical exceptions.

The 425-unit proposed adequate supply should be more than sufficient to meet future medical needs of patients and alleviate the need for future unit increases. Sales data submitted by the Licensed Non-Profit Producers for October-December (4th quarter) of 2020, showed that patients in the Medical Cannabis Program purchased on average 70.14 units during this three-month period. The proposed amount is 6 times greater than these sale records indicate. In addition, data from a recent study contracted by the New Mexico Department of Health (Cannabis Public Policy Consultants, 2021) showed very similar results. In this study, adult cannabis users from New Mexico reported consuming a total of about 78 grams (units) in a 90-day period.

It is also important to note that, with the passage of the Cannabis Regulation Act (CRA) in the 2021 Special Legislative Session and the imminent arrival of "commercial" cannabis sales (i.e., "adult use" or "recreational" sales) in New Mexico, the "adequate supply" limit will take on lesser significance. Once commercial sales begin, qualified patients in the Medical Cannabis Program will be able to exceed the "adequate supply" 90-day limit by making "commercial" purchases of cannabis. In this way, the adequate supply limit will cease to function as a true acquisition limit. Instead, the adequate supply limit will have two main functions: 1) to identify which cannabis purchases are tax-free, in accordance with the CRA; and 2) to identify the maximum quantity of cannabis that qualified patients and primary caregivers can collectively possess *outside* of a place of residence (given that the adequate supply limit exceeds the two-ounce limit that would otherwise apply outside of one's residence under the CRA). Pursuant to the CRA, there is no limit on the quantity of cannabis that can be possessed by an individual 21 years and older *inside* that person's residence.

D. <u>Recommendation Regarding Medical Cannabis Therapy for Seizures in Animals</u>

The Medical Cannabis Advisory Board considered a petition to add Medical Cannabis Therapy for Animals to the list of medical conditions qualifying for enrollment in the New Mexico Medical Cannabis Program. The Advisory Board recommended, by a vote of 8-0, that Medical Cannabis Therapy for Seizures in Animals should not be added to the list of qualifying medical conditions.

The New Mexico Board of Veterinary Medicine was contacted by the Advisory Board to understand what the Veterinary Board allows with regards to the use of cannabis in the treatment animals. The New Mexico Board of Veterinary Medicine stated that it follows the guidelines set forth by the American Veterinary Medical Association.

The American Veterinary Medical Association cites limited peer review and published information, lack of FDA-approval for therapeutic use, labeling concerns, and variable potency that could lead to toxicosis in the animal as reasons it does not authorize the use of cannabis in veterinary medicine.

New Mexico has legalized medical marijuana and recreational marijuana for human use only. Current laws do not authorize veterinarians to prescribe or recommend/certify medical marijuana for dog or cats in the state. If the goal is to allow licensed veterinarians to authorize the use of cannabis for animals, the petitioner should pursue legislative action to adopt laws specific to the regulation of cannabis and cannabis-derived product for veterinary patients. For the reasons stated, I am adopting the Advisory Board's recommendation to decline to add Therapy for Seizures in Animals as a qualifying condition in the Medical Cannabis Program.

II. Closing

I would like to thank the individuals who submitted petitions for consideration. I would also like to thank the Medical Cannabis Advisory Board for its continued work and support of this program.

-Docusigned by: David Scrase

David R. Scrase, M.D. Acting Cabinet Secretary

Nov 7, 2021 | 2:36 PM MST

Date

III. <u>References</u>

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Furthermore, in the communication, Secretary of Health David Scrase makes a blatantly false statement: "Once commercial sales begin, qualified patients in the Medical Cannabis Program will be able to exceed the 'adequate supply' 90-day limit by making 'commercial' purchases of cannabis. In this way, the adequate supply limit will cease to function as a true acquisition limit. Instead, the adequate supply limit will have two main functions: 1) to identify which cannabis purchases are tax-free, in accordance with the CRA; and 2) to identify the maximum quantity of cannabis that qualified patients and primary caregivers can collectively possess outside of a place of residence (given that the adequate supply limit exceeds the two-ounce limit that would otherwise apply outside of one's residence under the CRA)."

Secretary Scrase should confine his opinions to matters of medicine, because he is entirely mistaken on the law. As explained in my previous comments, the tax exemption portions of the Cannabis Regulation Act contain no volume limitation. There is simply no basis in statutory language to say that only the "adequate supply" volume is tax free. Furthermore, it is entirely outside the purview of DOH to make decisions regarding taxation. We will be informing legislators of this matter regarding taxation.

Thank you,

Kristina Caffrey

On Wed, Nov 10, 2021 at 10:52 AM comment, MCP, DOH <<u>MCP.Comment@state.nm.us</u>> wrote:

Thank you for 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: Kristina Caffrey <<u>kristina@ultrahealth.com</u>>
Sent: Tuesday, November 9, 2021 4:38 PM
To: comment, MCP, DOH <<u>MCP.Comment@state.nm.us</u>>
Subject: [EXTERNAL] Public Comments on Proposed Rule 7.34.3

CAUTION: This email originated outside of our organization. Exercise caution prior to clicking on links or opening attachments.

Good afternoon,

Attached are public comments sent regarding the Department of Health's proposed rule 7.34.3 NMAC.

Thank you,

Kristina Caffrey

--Kristina Caffrey Chief Legal Officer Ultra Health kristina@ultrahealth.com 505-401-7847 (cell)

This communication may be confidential and subject to the protection of attorney work product or attorney-client privilege. If you are not the intended recipient of this message, please notify the sender and do not disseminate this information.

--Kristina Caffrey Chief Legal Officer Ultra Health kristina@ultrahealth.com

505-401-7847 (cell)

This communication may be confidential and subject to the protection of attorney work product or attorney-client privilege. If you are not the intended recipient of this message, please notify the sender and do not disseminate this information.

From:	comment, MCP, DOH
То:	Sundberg, Andrea, DOH
Subject:	Fw: [EXTERNAL] Public Hearing November 12, 2021 (
Date:	Friday, November 12, 2021 3:51:12 PM

From: Duke Rodriguez <duke@ultrahealth.com>
Sent: Friday, November 12, 2021 2:42 PM
To: comment, MCP, DOH <MCP.Comment@state.nm.us>
Subject: [EXTERNAL] Public Hearing November 12, 2021 (

CAUTION: This email originated outside of our organization. Exercise caution prior to clicking on links or opening attachments.

Hearing Officer & Ms. Andrea Sundberg please accept the following written comments to be included with the rule making extended through the MCAB meeting December 2021:

It is embarrassing that we are participating in this rulemaking instead of waiting for the courts to properly adjudicate this issue. The Cannabis Regulation Act specifically states that any person may purchase 2 ounces of cannabis, 16 grams of cannabis extract and 800 milligrams of edible cannabis at any one time as of June 29, 2021. This matter has been fully briefed and sits before Judge Ben Chavez awaiting his ruling.

On June 29, 2021, DOH was stripped of any regulatory powers besides the patient registry. It is inappropriate for an agency that has been stripped of its powers to propose a rule to limit patient purchases below their statutory right, acting as if they are above the law and the Legislature.

The level of misinformation is frightening. The intentional misrepresentations about the price and availability of cannabis communicated to both the general public and the New Mexico Legislature are shameful beyond comprehension.

Why is DOH acting as the illegal gatekeeper between patients and their medicine? These rules are punitive for patients, not in accordance with law, and this rulemaking should be closed indefinitely.

Duke Rodriguez Ultra Health

From:	<u>comment, MCP, DOH</u>
To:	Sundberg, Andrea, DOH
Subject:	Fw: [EXTERNAL] Public Comment on Proposed Rule 7.34.3 - Public Hearing Nov. 12, 2021
Date:	Friday, November 12, 2021 4:27:23 PM
Attachments:	Patient Purchase Limits - Petition to initiate rulemaking process 03.25.2019.pdf
	NMDOH Response - Purchase limits 03.27.2019.pdf
	MCAB Petition Adequate Supply 03 29 2020 pdf

From: Kylie Safa <kylie@ultrahealth.com>
Sent: Friday, November 12, 2021 4:22 PM
To: comment, MCP, DOH <MCP.Comment@state.nm.us>
Subject: [EXTERNAL] Public Comment on Proposed Rule 7.34.3 - Public Hearing Nov. 12, 2021

CAUTION: This email originated outside of our organization. Exercise caution prior to clicking on links or opening attachments.

Good afternoon,

Please accept this as a written public comment for today's hearing regarding proposed rule 7.34.3.

As the original petitioner who was referenced repeatedly as the Department of Health's only source of evidence (I believe the Department referred to as a 'public submitted' petition, i.e., not originating with the Department) supporting the purchase limit increase, I feel it is important to set the record straight.

This particular petition to recommend an increase in patient purchase limits has a long history. The petition was originally submitted in March 2019 directly to the then Secretary of the DOH, Kathy Kunkel, as a petition to initiate a rulemaking process. Ms. Kunkel responded to said petition indicating the matter may be considered in the upcoming 2019 rulemaking to address plant count. Purchase limits were never considered during that 2019 rulemaking process as previously represented by then-Secretary Kunkel.

The petition was then submitted again to the Medical Cannabis Advisory Board (MCAB) in March 2020 for their consideration. The petition was not heard or voted on until November 2020, at which point the MCAB agreed with the petition's recommendation for increase to patient purchase limits. The petition sat idle with no action for nearly two years.

As you are aware, the entire landscape of cannabis in New Mexico has changed as of June 29, 2021 with the enactment of the Cannabis Regulation Act (CRA). The petition

to increase patient purchase limits is no longer relevant because (1) patient purchase limits were increased in statute, and (2) the DOH no longer has authority on anything cannabis related except the patient registry.

Had this proposed amendment to rule 7.34.4 occurred over two years ago when originally brought to the Department's attention, this would have been a victory for medical cannabis patients. In today's world however, it is nothing short of a slap in the face to New Mexico's medical cannabis patients. It is an illegal attempt to impede on the rights provided to all persons over the age of 21 under the CRA, patients included. It is an illegal attempt to create a taxing scheme in which the Department has no authority.

All petitions and responses mentioned in this comment are attached to be included in the public record.

Thanks,

Kylie Safa Chief Operating Officer 255 Camino Don Tomas Bernalillo, NM 87004 Phone: (415) 250-8564



Ultra Health

March 25, 2019

VIA Mail and Email

Kathyleen M. Kunkel Kenny Vigil New Mexico Department of Health P.O. Box 26110 1190 St. Francis Dr., Suite N-4095 Santa Fe, NM 87502-6110 Kathy.Kunkel@state.nm.us KennyC.vigil@state.nm.us

Re: Patient Purchase Limits - Petition to Initiate Rulemaking Process

Dear Secretary Kunkel,

Pursuant to Rule 1.24.25.10 NMAC, New Mexico Top Organics-Ultra Health, Inc. (Ultra Health) petitions the Department of Health to initiate a rulemaking regarding patient purchasing limitations, specifically to raise the patient purchase limitation to the common industry limit of 15 ounces in any three-month period; and eliminate the use of units as a system of measurement altogether, in exchange for the industry standard measurement of dry weight in ounces for flower and dry weight in ounces of THC for extracts and infused products.

As you may know, Rule 1.24.25.10 NMAC allows "any person" to "file a petition for rulemaking with an agency."

Ultra Health recently discussed with Department staff the potential for building a more robust medical cannabis program for patients in New Mexico. One of the subjects we discussed was that most other states with medical cannabis programs have standards for patient purchase limitations that are far more accommodating than New Mexico's.

Ultra Health has reason to believe that a reevaluation of patient purchase limitations will better the health and quality of life for the 70,000+ New Mexicans currently enrolled in the medical cannabis program.

Existing Rule Regarding Patient Purchase Limitations

The current rule regarding patient purchase/possession limitations is Rule 7.34.3.9 NMAC, which states, "A qualified patient and a qualified patient's primary caregiver may collectively possess within any three-month period a quantity of usable cannabis no greater than 230 total units. For purposes of department rules, this quantity is deemed an adequate supply." This roughly translates to 8 ounces, or 230 grams, per 90 days.

To calculate a unit, "one unit of usable cannabis shall consist of one gram of dried leaves and flowers of the female cannabis plant, or 0.2 grams (200 milligrams) of THC for cannabis derived products." Rule 7.34.3.9 NMAC.

There are exceptions allowed if the patient can produce "a statement by a medical practitioner explaining why a greater number of units of usable cannabis, or a higher concentration of THC in concentrated cannabis-derived product, is medically necessary." Rule 7.34.3.9 NMAC.

Proposed Rule in Underline and Strikethrough Format

The underlined material indicates new language, the strikethrough material indicates language to be removed.

7.34.3.9 QUANTITY OF USABLE CANNABIS THAT MAY BE POSSESSED BY A QUALIFIED PATIENT OR PRIMARY CAREGIVER:

A. **Maximum quantity:** A qualified patient and a qualified patient's primary caregiver may collectively possess within any three-month period a quantity of usable cannabis no greater than <u>15 ounces</u>. <u>230 total units</u>. For purposes of department rules, this quantity is deemed an adequate supply. (For ease of reference: <u>230 units is equivalent to 230 grams, or approximately eight ounces, of dried usable cannabis plant material.) A qualified patient and primary caregiver may also possess cannabis seeds.</u>

B. <u>Dry weight measurement</u>: <u>Calculation of units</u>: For purposes of department rules, <u>dried usable cannabis plant material shall be measured in ounces, and all cannabis-derived products shall be measured by the dry weight of THC content in milligrams.</u> one unit of usable cannabis shall consist of one gram of the dried leaves and flowers of the female cannabis plant, or 0.2 grams (200 milligrams) of THC for cannabis-derived products.

C. Maximum THC content of concentrates: A qualified patient or primary caregiver shall not possess a concentrated cannabis-derived product that contains greater than seventy percent (70%) THC by weight.

D. Medical exception: A greater quantity of usable cannabis, not to exceed 115 additional grams units, may be allowed, and a concentrated cannabis-derived product with THC content greater than seventy percent (70%) by weight may be allowed, at the department's discretion, upon the submission of a statement by a medical practitioner explaining why a greater <u>amount number of units</u> of usable cannabis, or a higher concentration of THC in concentrated cannabis-derived product, is medically necessary. Any such allowance shall be reviewed for approval by the program's medical director.

Legal Authority Authorizing the Agency to Adopt the Rule

The Department of Health does have explicit statutory authority to create and adopt a rule regarding patient purchase/possession limitations. This statutory authority is shown by several interlocking provisions of the Lynn and Erin Compassionate Use Act. First, NMSA 1978 §26-2B-4(A) states, "A qualified patient shall not be subject to arrest, prosecution or penalty in any manner for the possession of or the medical use of cannabis if the quantity of cannabis does not exceed an adequate supply." This provision indicates there is and should be a cap on the amount of cannabis a qualified patient may *lawfully* purchase.

Second, NMSA 1978 §26-2B-3(A) explicitly defines "adequate supply" as "an amount of cannabis, in any form approved by the department, possessed by a qualified patient or collectively possessed by a qualified patient and the qualified patient's primary caregiver that is determined by rule of the department to be no more than reasonably necessary to ensure the uninterrupted availability of cannabis for a period of three months and that is derived solely from an intrastate source"

Reading §26-2B-4(A) and §26-2B-3(A) together indicates the Legislature intended a limitation on the amount of cannabis a qualified patient could possess/purchase, and that the limitation should be based upon necessity and availability.

Finally, NMSA 1978 §26-2B-7(A)(2) explicitly directs and allows DOH to promulgate rules to "define the amount of cannabis that is necessary to constitute an adequate supply, including amounts for topical treatments." This ties in with the previously cited sections to give DOH authority to set the limitation point for patient purchase/possession.

Basis for Proposed Rule

Ultra Health believes now is an appropriate time to reevaluate the patient purchase limitation rule, because the patient purchase limitation rule may require some patient survey data. If DOH plans to survey patients on other medical cannabis-related subjects (such as consumption patterns), DOH could also address the purchase limitation rule within that survey. Additionally, as DOH is working diligently to promulgate a new rule regulating plant count, it should be noted that a change in patient purchase limits will directly affect how many plants producers will need to meet patient demand. Therefore, it seems reasonable to address these issues simultaneously, to ensure consistency between supply and demand.

The use of units as a means of measurement is unique to New Mexico. Every other state's medical cannabis program regulates purchase limits through more technical means of measurement (i.e. ounces, milligrams). The "calculation of units" as described in Rule 7.34.3.9 NMAC, does not serve the medical cannabis program well and is a common source of confusion for medical cannabis program participants. It also creates logistical complications with the State used tracking system. A conversion from units to ounces is the simplest, most timely, and cost-efficient solution for accurate tracking of transactions. It would benefit the program, and the program's patients, to have more accurate tracking and collect more meaningful data.

As DOH knows, the medical cannabis program has undergone significant change in the years since the program was first implemented in 2007. One of the most significant changes is the expansion of available products. Whereas in 2007, most patients were simply purchasing the unprocessed dried flower material to smoke, more and more patients now prefer more sophisticated cannabis products, both smokable and non-smokable. For example, the medical market in Colorado experienced a 100% increase in concentrate use between the years 2014 and 2017 (Orens, Light, Lewandowski, Rowberry, and Saloga, 2018, p. 23). For the purpose of tracking purchases, supply of these products can be defined in terms of milligrams of dry weight THC content, as is the industry standard. Milligrams are consistent with the avoirdupois ounce, allowing for simple conversions and tracking.

Example Purchases:

First Purchase:1 oz flower + 1500 mg concentrate + 200 mg edible = 1 oz + 1700 mg1 oz flower + 0.053 oz concentrate + 0.007 oz edible = 1.06 oz usable cannabis15 oz purchase limit - 1.06 oz purchased = 13.94 oz remaining purchase limitSecond Purchase:2 oz flower + 500 mg concentrate + 1000 mg edible = 2 oz + 1500 mg2 oz flower + 0.018 oz concentrate + 0.035 oz edible = 2.053 oz usable cannabis13.94 oz purchase limit - 2.053 oz purchased = 11.887 oz remaining purchase limitThird Purchase:

 $\overline{0.5 \text{ oz flower} + 6000 \text{ mg concentrate} + 60 \text{ mg edible} = 0.5 \text{ oz} + 6060 \text{ mg}}$ 0.5 oz flower + 0.212 oz concentrate + 0.002 oz edible = **0.714 oz usable cannabis**

11.887 oz purchase limit – 0.714 oz purchased = 11.173 oz remaining purchase limit

Additionally, as cannabis producers have become more experienced and refined their methods, patients have also become more knowledgeable about their needs and consumption habits. DOH has not performed a patient survey since 2013, and given the significant changes in the program, a study on consumption and need patterns seems due.

Another important factor in the discussion on patient limits is Rule 7.34.4.8 NMAC. This rule allows patients with personal production licenses "to possess no more than four mature female plants and a combined total of 12 seedlings and male plants, and may possess no more than an adequate supply of usable cannabis, as specified in department rule." Patients with PPLs can easily cultivate more than 8 ounces with the plant allotment allowed by rule. Therefore, patients who do not choose to cultivate on their own should be allowed to purchase enough medicine to meet their needs. Ultra Health believes patients should be allowed 15 ounces over a 90-day timeframe, which is in line with the amount patients can buy in other medical markets.

Raising the purchase limits should increase incentive and accessibility for patients to purchase from a lawful, regulated source. When patients are restricted in the regulated system,

from purchasing the quantities necessary to alleviate their symptoms, they have three options, (1) suffer through their debilitating medical condition until they are able to visit a practitioner, receive their statement, mail their statement to DOH, and await notice of an increase from DOH, (2) purchase from the illicit market where they are not restricted by purchase limits, but risk incurring criminal and civil penalties, and the potential to consume contaminated products, or (3) purchase from a regulated market in another state that has higher purchase limits than New Mexico, and risk federal drug trafficking charges upon returning to New Mexico as well as criminal and civil penalties. Increased purchase limitations will resolve this accessibility concern for patients, while also reducing DOH's administrative responsibilities.

State	Purchase limits (oz)	Supply period	3-month supply period (oz)	
Arizona	2.5	14 days	15	
AZ Rev Stat § 36-2806.02 (2016)				
Colorado	2	At any time	*NC	
Title 25 Health § 25-15-106 (g)(I)				
Illinois	2.5	14 days	15	
410 ILCS 130/10(a)				
Maine	2.5	"At any one time"	NC	
10-144 CMR ch.122 § 1(k)				
Nevada	2.5	14 days	15	
NRS 453A.200 (3)(B)				
Oklahoma	3	"A single	NC	
310:681-5-12		transaction"		
Oregon	24	May possess at	NC	
333-008-0080		any one time		
Washington	3	1 day	270	
RCW 69.50.357		-		

New Mexico's patient purchase limitations are much more restrictive than those of other states. The following is a breakdown of how other states deal with the needs of their medical cannabis patients:

**NC* = *Not comparable*

New Mexico appears to be the only state with such scant purchase limits. These examples indicate that other states are able to maintain regulatory control of their programs even with higher purchase limitations, and without the use of a fabricated unit of measurement. If sustaining a robust medical cannabis program is the objective, we should try to be more compassionate towards patient needs. The purchase limitations of other states are far more reflective of actual need than New Mexico's stringent eight ounces. These examples also show that Ultra Health's recommended 15 ounces per any 3-month period is in keeping with the industry practice.

Ultra Health would be happy and willing to further discuss the data, the experience of other states, and the range of products it currently offers, so that DOH can better understand the

issue of patient purchase limitations and the complications that arise from the use of units as a system of measurement.

Rulemaking Process

Rule 1.24.25.10 NMAC requires an agency which has received a petition to initiate rulemaking to grant or deny the petition. If the agency denies the petition, it must "issue a concise written statement explaining its reason for denial." Ultra Health looks forward to receiving the position of DOH regarding rulemaking for patient purchase limitations.

Respectfully,

Kylie Safa Project Manager Ultra Health 255 Camino Don Tomas Bernalillo, NM 87004

Cc: Kristina Caffrey, Attorney, Egolf, Ferlic, Martinez & Harwood, LLC

Arizona Legislature. (n.d.). Retrieved from

https://www.azleg.gov/viewdocument/?docName=http://www.azleg.gov/ars/36/02806-02.htmColorado Revised Statutes Title 25. Health § 25-1.5-106. (n.d.). Retrieved from https://codes.findlaw.com/co/title-25-health/co-rev-st-sect-25-1-5-106.html

Illinois General Assembly. (n.d.). Retrieved from http://www.ilga.gov/legislation/ilcs/ilcs3.asp?ActID=3503&ChapterID=35

Maine <u>https://www.maine.gov/dafs/bbm/mmmp/sites/maine.gov.dafs.bbm.mmmp/files/inline-files/2018-MMP-Rules-1111.pdf</u>

NAC: CHAPTER 453A - MEDICAL USE OF MARIJUANA. (n.d.). Retrieved from https://www.leg.state.nv.us/NAC/NAC-453A.html

Oklahoma Department of Health 310 § 681-1-8. Retrieved from http://omma.ok.gov/Websites/ddeer/images/310-681%20EME2%20Medical%20Marijuana%20Rules%208-1-18%20wRedMark%20Revisions.pdf

Oregon Health Authority 333-008-0080. Retrieved from https://www.oregon.gov/oha/ph/diseasesconditions/chronicdisease/medicalmarijuanaprogram/pa ges/top20.aspx#patientlimits

Orens, A., Light, M., Lewandowski, B., Rowberry, J., & Saloga, C. (2018). *Market Size and Demand for Marijuana in Colorado 2017 Market Update*(Rep.). Denver, CO: Marijuana Policy Group. doi:https://www.colorado.gov/pacific/sites/default/files/MED Demand and Market Study 082018.pdf

Washington State Legislature RCW <u>69.50.357</u>. Retrieved from https://app.leg.wa.gov/RCW/default.aspx?cite=69.51A.210

MICHELLE LUJAN GRISHAM GOVERNOR



KATHYLEEN M. KUNKEL CABINET SECRETARY

<u>Via U.S. Postal Mail</u>

March 27, 2019

Kylie Safa Project Manager Ultra Health 255 Camino Don Tomas Bernalillo, NM 87004

Dear Ms. Safa:

The New Mexico Department of Health (Department) is in receipt of your petition dated March 25, 2019, which seeks to initiate the rulemaking process with respect to changes that you proposed to the Department's rule 7.34.3.9 NMAC. By this letter, the Department denies the petition. In accordance with 1.24.25.10(C) NMAC, this letter shall serve as the Department's concise written statement explaining the reason for the denial.

As you know, the Department of Health is currently in the process of surveying patients and producers to gather more information relevant to supply and demand of medical cannabis within the NM Medical Cannabis Program. The Department recently adopted an emergency rule amendment to 7.34.4.8 NMAC, increasing the plant limit to 2,500 from the previous figure of 450. We anticipate using the feedback obtained from patients and producers to arrive at a final rule with respect to the plant limit identified in 7.34.4.8 NMAC. We also anticipate possibly using that feedback to address other subject areas in the rule, including the 3-month "adequate supply" usage and possession limit that is specified at 7.34.3.9 NMAC.

However, at this time, the patient and producer surveys have not been completed. We believe that it would be premature to pursue amendments to the affected Medical Cannabis Program rules without having yet received this important stakeholder input. As always, the Department appreciates your interest with respect to the Program, and we ask that you submit comment in the course of the upcoming rule hearing, for consideration by the hearing officer and incorporation into the hearing officer's report. At this time, we anticipate that the rule hearing will likely be held in late June of this year.

for m Kurle Sincerely,

Kathy Kunkel Cabinet Secretary



OFFICE OF THE SECRETARY 1190 St. Francis Dr., Suite N4100 • P.O. Box 26110 • Santa Fe, New Mexico • 87502 (505) 827-2613 • FAX: (505) 827-2530 • www.nmhealth.org



March 29, 2020

VIA Email and Hand Delivery

Medical Cannabis Advisory Board Department of Health Medical Cannabis Program 1474 Rodeo Road Suite 200 Santa Fe, NM 87502

Petitioner

Ultra Health 255 Camino Don Tomas Bernalillo, NM 87004 415-250-8564

Re: Petition to recommend quantities of cannabis that are necessary to constitute an adequate supply for qualified patients and primary caregivers

Dear Medical Cannabis Advisory Board Member,

On behalf of the petitioner, Ultra Health, 255 Camino Don Tomas, Bernalillo, N.M., 87004, we respectfully submit the following petition for your consideration. This submission includes all required sections defined by the Department of Health, to the extent that it does not include material specifically required for a petition related to a newly requested qualifying medical condition. The petition is submitted in accordance with NMSA 1978 §26-2B-6(E). The

index of materials are as follows (due to the number of attachments and size of files, I have attached three files electronically and have provided links for other referenced materials):

.....

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Existing Rule Reg	arding Adequate Supply	4
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Introduction

Pursuant to Rule 1.24.25.10 NMAC, New Mexico Top Organics-Ultra Health, Inc. (Ultra Health) previously petitioned the Department of Health to initiate a rulemaking regarding patient purchase and possession limitations, specifically to raise the patient purchase and possession limitation to the common conservative industry standard of 15 ounces (or 420 units if continuing current methodology of tracking) in any three-month period.

In connection with that written petition submitted on March 25, 2019, over one year ago, Ultra Health provided extensive objective data and evidence to the Department of Health Secretary Kathy Kunkel to increase patient purchase and possession limitations to a more reasonable and conservative industry standard of no less than 15 ounces (or 420 units if continuing current methodology of tracking) in any three-month period. Secretary Kathy Kunkel responded to the aforementioned petition indicating that the DOH intended to revisit adequate supply in the then upcoming rulemaking regarding plant limits.

Unfortunately, this gaping issue in our Medical Cannabis Program has still not been addressed, despite Secretary Kunkel's response; despite two extensive rulemaking processes being initiated; and despite patient surveys conducted by Research and Polling, Inc., on behalf of the NMDOH, indicating the need for an increase in the allowed purchase limits. The Secretary's response indicated a willingness to review the matter, conditional on accomplishing the survey and the survey results (response attached). Sufficient time has expired and it is incumbent on the Medical Cannabis Advisory Board to properly consider the matter.

Governor Lujan Grisham has stated time and time again that she is committed to the need for a more robust medical cannabis program. Ultra Health provides sufficient evidence in this petition to support that an increase in the amount currently determined to what constitutes adequate supply will better the health and quality of life for the 82,000+ New Mexicans currently enrolled in the medical cannabis program and create the robust medical cannabis program the Governor has pledged.

Comparatively, the record is very clear on how reasonable other states have been in establishing their purchase and possession limits for medical cannabis patients. Of the 33 states with medical cannabis programs, only Ohio comes close to matching New Mexico's 230 units per 90 days, but even the Ohio model has broken it further into tiers and a possession limit on the amount of THC (dry weight) at any one time which potentially could provide amounts greater amounts than New Mexico, particularly when applying to purchases of concentrates and edibles. Thus, New Mexico clearly falls to last in the country for those medical cannabis programs allowing for THC above 0.5%, and is not consistent with the Governor's expectation of a industry leading robust medical cannabis program.

The disparity is even more glaring when compared regionally with surrounding states. New Mexico's purchase and possession limit as determined for an adequate supply clearly needs an immediate increase. By example, Oklahoma has the most generous program allowing 270 ounces over 90 days, followed by Colorado at 180 ounces over 90 days, and then Arizona and Nevada both at 15 ounces over 90 days. Interestingly, one of the more conservative states in the region is Utah and their program officially initiated dispensensing activities on March 1, 2020. Just weeks old, Utah became the most recently launched program in the U.S., and is allowing patients to possess 12 ounces in a 90-day period, which is 50% higher than what New Mexico patients are legally allowed to access. New Mexico must immediately update the amount deemed to be an adequate supply.

Advisory Board Statutory Duty to Recommend Quantities Regarding Adequate Supply

NMSA 1978 §26-2B-3(A) explicitly defines "adequate supply" as "an amount of cannabis, in any form approved by the department, possessed by a qualified patient or collectively possessed by a qualified patient and the qualified patient's primary caregiver that is determined by rule of the department to be no more than reasonably necessary to ensure the uninterrupted availability of cannabis for a period of three months and that is derived solely from an intrastate source".

The medical cannabis advisory board has the statutory authority and the duty to recommend amounts of cannabis qualified patients may purchase and possess. The Lynn and Erin Compassionate Use Act explicitly lists advisory board duties. NMSA 1978 §26-2B-6(E) states, "The advisory board shall: (...) E. recommend quantities of cannabis that are necessary to constitute an adequate supply for qualified patients and primary caregivers" (emphasis added).

Ultra Health respectfully requests that the advisory board uphold their statutory duty to recommend quantities of cannabis to constitute an adequate supply and, for the reasons stated within this petition, recommend a minimum of 15 ounces (420 units) of usable cannabis for a period of three months.

Existing Rule Regarding Adequate Supply

The current rule regarding patient possession and adequate supply is Rule 7.34.3.9 NMAC, which states, "A qualified patient and a qualified patient's primary caregiver may collectively possess within any three-month period a quantity of usable cannabis no greater than 230 total units. For purposes of department rules, this quantity is deemed an adequate supply." This roughly translates to 8 ounces, or 230 grams, per 90 days.

To calculate a unit, "one unit of usable cannabis shall consist of one gram of dried leaves and flowers of the female cannabis plant, or 0.2 grams (200 milligrams) of THC for cannabis derived products." Rule 7.34.3.9 NMAC.

There are exceptions allowed if the patient can produce "a statement by a medical practitioner explaining why a greater number of units of usable cannabis is medically necessary." Rule 7.34.3.9 NMAC.

Proposed Rule in Underline and Strikethrough Format

The underlined material indicates new language, the strikethrough material indicates language to be removed.

7.34.3.9 QUANTITY OF USABLE CANNABIS THAT MAY BE POSSESSED BY A QUALIFIED PATIENT OR PRIMARY CAREGIVER:

A. Maximum quantity: A qualified patient and a qualified patient's primary caregiver may collectively possess within any three-month period a quantity of usable cannabis no greater than $\frac{230}{420}$ total units. For purposes of department rules, this quantity is deemed an adequate supply. (For ease of reference: $\frac{230}{420}$ units is equivalent to $\frac{230}{420}$ grams, or approximately eight fifteen ounces, of dried usable cannabis plant material.) A qualified patient and primary caregiver may also possess cannabis seeds.

B. Calculation of units: For purposes of department rules, one unit of usable cannabis shall consist of one gram of the dried leaves and flowers of the female cannabis plant, or 0.2 grams (200 milligrams) of THC for cannabis-derived products.

C. Medical exception: A greater quantity of usable cannabis, not to exceed 115 additional units, may be allowed, at the department's discretion, upon the submission of a statement by a medical practitioner explaining why a greater number of units of usable cannabis is medically necessary. Any such allowance shall be reviewed for approval by the program's medical director.

Reasoning for Rule Change and Increased Adequate Supply

I. NEW MEXICO'S LIMITS ARE ABNORMALLY RESTRICTIVE

New Mexico's patient purchase limitations are much more restrictive than those of other states. The following is a breakdown of how other states' medical cannabis programs address the needs of their medical cannabis patients:

State	Purchase limits (oz)	Supply period	3-month supply period (oz)
Arizona	2.5 ounces	14-day period	15 ounces
Arkansas	2.5 ounces	14-day period	15 ounces
Colorado	2 ounces	At any time	180 ounces

Hawaii	4 ounces	15-day period	24 ounces
Illinois	2.5 ounces	14-day period	15 ounces
Maine	2.5 ounces	15-day period	15 ounces
Nevada	2.5 ounces	14 days	15 ounces
Oklahoma	3 ounces	"A single transaction"	270 ounces
Oregon	24 ounces	May possess at any one time	
Utah	4 ounces	30-day period	12 ounces
Washington	3 ounces	1 day	270 ounces

New Mexico appears to be the only state with such scant purchase limits. These examples indicate that other states are able to maintain regulatory control while offering patients access to cannabis in quantities sufficient to meet their medical needs.

New Mexico's purchase limits are an outlier and one should not assume that New Mexican patients simply use or need less medicine than the patients of other states. It is more reasonable to assume that patient acuity should be comparable between states unless the NMDOH can point to specific patient data to suggest otherwise. What can also be safely assumed is that patients with unmet needs in the regulated market are seeking relief from the illicit markets.

The purchase limitations of other states are far more reflective of actual need than New Mexico's stringent eight ounces. These examples also show that Ultra Health's recommended 15 ounces per any 3-month period is in keeping with the industry practice.

II. PATIENT SURVEY RESPONSES INDICATE NEED FOR HIGHER LIMITS

In May 2019 the DOH conducted a patient survey in connection with determining adequate supply and producer plant limits. On page 32 of the survey there are two important statistics worth noting here:

- When asked, "Would you purchase more cannabis or cannabis-derived products in a 90-day period if allowed?" Of the patients surveyed:
 - 48% answered YES
 - 49% answered NO
 - 3% don't know/won't say
- When asked, "Have you built up a tolerance to cannabis or cannabis products in the past year?" Of the patients surveyed:
 - 24% answered YES
 - 73% answered NO
 - 3% don't know/won't say

Nearly half of patients surveyed have indicated they would purchase more medicine in a 90-day period if allowed, therefore indicating a need for higher patient purchase limits. At its current enrollment of over 82,000+ patients, the survey indicates over 39,000 patients' needs are not met under the 230 unit limit.

In addition, one-quarter of patients have reported they developed a tolerance to cannabis during the past year, which indicates a greater need for purchase limits to be adjusted to accommodate tolerance to the medicine. Per the survey, this indicates nearly 20,000 patients could benefit from an adjustment to purchase limits and allow those patients to receive the beneficial use of medical cannabis as established within the purpose of the Lynn and Erin Compassionate Use Act to treat their debilitating medical condition.

III. DISCREPANCY BETWEEN QUALIFIED PATIENTS' POSSESSION LIMITS

Another important factor in the discussion on patient limits is the discrepancy that currently exists between qualified patients with a personal production license (PPL) and those without. NMSA 1978 §26-2B-4(A) states, "A qualified patient or a qualified patient's primary caregiver shall not be subject to arrest, prosecution or penalty in any manner for the possession of or the medical use of cannabis if the quantity of cannabis does not exceed an adequate supply; provided that a qualified patient or the qualified patient's primary caregiver may possess that qualified patient's harvest of cannabis."

Rule 7.34.4.8 NMAC states, "A qualified patient or primary caregiver who holds a valid personal production license is authorized to possess no more than four mature female plants and a combined total of 12 seedlings and male plants, and may possess no more than an adequate supply of usable cannabis, as specified in department rule; provided that a qualified patient or qualified patient's primary caregiver may possess that qualified patient's harvest of cannabis. A personal production license holder may additionally obtain usable cannabis, seeds, or plants from licensed non-profit producers."

Patients with PPLs could potentially cultivate more than the eight ounces deemed to constitute an adequate supply with the plant allotment allowed by rule. Patients with PPLs are also, rightfully so, allowed to purchase their full 230 units through the dispensary. This creates a huge disparity between classes of patients, all of whom deserve equal protection under the law. Increasing possession limits is the first step towards creating that equality and meeting *all* patients' needs.

IV. ACCESSIBILITY TO SAFE, LAWFUL, AND REGULATED MEDICINE

Raising the purchase limits should increase incentive and accessibility for patients to purchase from a lawful, regulated source. When patients are restricted in the regulated system, from purchasing the quantities necessary to alleviate their symptoms, they have limited and less than ideal options.

One option is to suffer through their debilitating medical condition until they are able to visit a practitioner, receive their statement, mail their statement to DOH, and await notice of an increase from DOH that still may not be sufficient to meet their needs.

Another option is to travel over state lines and purchase from a regulated adult-use market that has higher purchase limits than New Mexico, and risk federal drug trafficking charges upon returning to New Mexico as well as criminal and civil penalties.

Another option is to purchase from the illicit market where patients are not restricted by arbitrary purchase limits, but risk incurring criminal and civil penalties, and the potential to consume contaminated products potentially worsening their debilitating medical conditions.

"The purpose of the Lynn and Eric Compassionate Use Act is to allow for the beneficial use of medical cannabis in a regulated system for alleviating symptoms of debilitating medical conditions and their medical treatments." None of the options listed above meet the purpose of the Act. Increased purchase limits will resolve this accessibility issue for patients and will allow for the beneficial use of medical cannabis.

Finally, in 2019 the Legislature and the Governor have made their position clear by adopting in statute "...a qualified patient's use of cannabis pursuant to the Lynn and Erin Compassionate Use Act shall be considered the equivalent of the use of any other medication under the direction of a physician and shall not be considered to constitute the use of an illicit substance or otherwise disqualify a qualified patient from medical care." In keeping with the spirit of the law, it would seem logical to allow deference to patient-need over archaic views to the use of medical cannabis as an illicit substance. Many of today's New Mexico caps on the medical cannabis program, including patient limits are an outgrowth of a 'war on drugs' mentality and not based on science or the community standard of care when measured against other more rational state approved programs.

V. COVID-19 IMPACT ON PATIENT NEEDS

Again, the most commonly accepted, conservative industry standard for patient purchase limits equates to 15 ounces in a 90-day period. The advisory board should recommend to the Department an increase in patient purchase limits to no less than 15 ounces over 90 days to ensure patients can purchase back-stock medicine allowing them to meet the CDC's recommendation to have a 30-day supply of medicine on hand. This will also aid in reducing unnecessary dispensary foot traffic, limiting unnecessary travel, particularly in rural areas, limiting travel to other states for cannabis needs, and reducing illicit market activity where patients are dangerously exposed to contracting COVID-19.

Increased consumption of medical cannabis is a predictable outgrowth of the current environment, particularly because <u>85% of patients</u> enrolled in the New Mexico medical cannabis program have the qualifying conditions of PTSD (52%) or chronic pain (33%). These vulnerable populations need medical cannabis now more than ever. Increased anxiety and depression, deviation from normal day-to-day life, mental impact of being homebound, stress over loss of income, loss of access to other therapeutic treatments (i.e. water therapy, massage therapy, group therapy, etc.) all of these factors and more are contributing to cannabis patients' increased consumption needs as they seek some manner of relief during these trying times.

Summary/Conclusions

The New Mexico Medical Program was approved in 2007 and suffered from limited patient growth and heavy-handed regulations for a number of years under the previous administration of Governor Susana Martinez. Thankfully, the medical cannabis program has benefitted from a national discourse on the acceptability of medical cannabis, favorable court decisions in New Mexico triggering more dispensary locations and additional plants in production, expansion in the number of qualifying conditions, and an increased patient awareness/acceptability statewide.

During the eight years of Governor Martinez's administration a number of notable activities happened in surrounding states with regard to cannabis, including the legalization of the adult-use and sale in Colorado, approval and launching of both the medical cannabis program and adult-use in Nevada, and near passage of an adult-use program in Arizona. The vote failed in Arizona by 22,000 votes but the hotly contested campaign caused a surge in the medical cannabis program and now stands at nearly 230,000 cardholders.

More recently, during the new administration of Governor Michelle Lujan Grisham, the surrounding states have seen continued progressive evolution in the programmatic design of their medical cannabis programs. Oklahoma has put forth the most patient-friendly medical cannabis model in the region which has resulted in a soaring program of over 258,000 patients in the first year alone. Utah has joined the ranks of surrounding state approved medical cannabis programs by launching their model on March 1, 2020.

In all surrounding states with medical cannabis programs allowing for THC above 0.5%, New Mexico lags significantly in the approved amount of cannabis deemed necessary to constitute an adequate supply for qualified patients and caregivers. New Mexico's shortage in the allowance granted to patients creates an absurd and unreasonable result in which patients cannot adequately medicate without reliance on illicit, unregulated purchases from either surrounding states or the black market. Utah allows 50% more per medical patient than New Mexico. Nevada and Arizona allow 100% more per patient than New Mexico. Colorado and Oklahoma allow medical patients to buy more in as little as three days than New Mexicans can buy over three months. In fact, Oklahomans are allowed to purchase nearly 3,300% more per patient or 33 times what a similar patient would be allowed in New Mexico.

The purpose of the program is to serve the needs of all medical cannabis patients, not just a few. In order for the program to function and for the statutory purpose of the beneficial use of cannabis to be met, the rules on adequate supply need to reflect every patient's needs and provide for a robust program that allows patients to acquire more medicine if their debilitating condition calls for it. A program that does not allow patients to purchase what they need frustrates the purpose of the statute and forces otherwise legal participants to seek medicine from the black market, where cannabis can pose serious health risks that can be completely avoided if the department were to provide adequate patient purchase limits.

Whether considered individually or collectively, each element listed here justifies the need for increased adequate supply. New Mexico has abnormally restrictive state limits

compared with other medical cannabis programs nationally and regionally. There's a proven need for change demonstrated by patient voices in a survey produced by an independent polling contractor and provided by the NMDOH. There exists a discrepancy and inequality between the category of patients within New Mexico, those with a personal production license and those without. There is a legal obligation to provide safe, accessible medicine from the lawful regulated industry that is not being wholly met. Lastly, though certainly not least important, the unknown short to long term implications of COVID-19 on our medically vulnerable 82,000+ patients should cause us to reevaluate what is right for the patients. The need for change is clear.

We respectfully request the Medical Cannabis Advisory Board increase adequate supply to a minimum of the conservative industry standard of 15 ounces (or 420 units) for a three-month period. Ideally, the Medical Cannabis Advisory Board should commit to reviewing adequate supply annually and make recommendations for its adjustment as the program progresses.

Thank you for your time and consideration on this matter.

Kylie Safa, Chief Operating Officer, Ultra Health®

Supporting Documents (provided via electronic attachment)

03 25 19 Petition to Initiate Rulemaking Process

NMDOH Response - Purchase limits

Medical Cannabis Patient Survey, May 2019

Citations

Arizona:

https://www.azleg.gov/viewdocument/?docName=http://www.azleg.gov/ars/36/02806-02.htm

Arkansas: https://www.healthy.arkansas.gov/programs-services/topics/medical-marijuana-fags

Colorado: https://codes.findlaw.com/co/title-25-health/co-rev-st-sect-25-1-5-106.html

Hawaii: https://health.hawaii.gov/medicalcannabis/files/2018/07/Act-116-18.pdf

Illinois: http://www.ilga.gov/legislation/ilcs/ilcs3.asp?ActID=3503&ChapterID=35

Maine:

https://www.maine.gov/dafs/bbm/mmmp/sites/maine.gov.dafs.bbm.mmmp/files/inline-files/2018 -MMP-Rules-1111.pdf

Ohio: http://codes.ohio.gov/oac/3796:8-2-04v1

Oklahoma:

http://omma.ok.gov/Websites/ddeer/images/310-681%20EME2%20Medical%20Marijuana%20R ules%208-1-18%20wRedMark%20Revisions.pdf

Oregon:

https://www.oregon.gov/oha/ph/diseasesconditions/chronicdisease/medicalmarijuanaprogram/pages/top20.aspx#patientlimits

Utah: https://le.utah.gov/~2018S3/bills/static/HB3001.html

Washington: https://app.leg.wa.gov/RCW/default.aspx?cite=69.51A.210