

[EXT]

Chad Lozano <chadavidlozano@gmail.com>

Fri 6/21/2019 3:44 PM

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

Hello, I know the hearing is a few weeks away, but I wanted to just chime in with my two cents ahead of time.

The biggest thing I want to address during this rules hearing is the PPLs, and of course the new plant count limit for the LNPPs.

Before I begin I would like to thank all of you for being supportive, [REDACTED]

[REDACTED]

My first concern is of course the landlord clause, [REDACTED] My understanding is it was placed there because of a "asset forfeiture" law. That law was changed a few years ago, so that fear is no longer real in New Mexico. On top of that concern on the paperwork to obtain your PPLs it says that no one can no where it is. see it from a street etc [REDACTED]

I believe growing should be between the tenant and the landlord, if they do not want cannabis grown at that property, they can simply place it in the requirements to rent, and the contract if need be. I have seen this happen in Colorado, even when looking some places will specify no cannabis growing on property, so it's already implemented elsewhere. If we rid of the PPL, and just allow everyone with a card to grow cannabis, it will free up the DoH to process more cards and be able to make the 30 day deadline, that i'm sure we are all aware is the law. Also charging a patient who can barely afford to buy their cannabis from a store, just to be able to grow their own cannabis seems a little discriminatory to me, also the 50 dollar charge for replacement is a bit much as well. when anyone without a PPL isn't charged anything for the card. or for a replacement. [REDACTED]

[REDACTED] you will actually make about \$100,000 more charging 5 dollars for 72K+ patients (and growing) vs \$30 for 7,000 patients who have PPLs. That only increases revenue with more patients who join the program. I understand there is a concern about the black market, but the patients who now have PPLs don't grow that much, and only about 10% of them actually grow, and even less, about 1% actually know how to grow well enough to supply them throughout the year. Having a PPL just means Im allowed to grow, but it doesn't mean that I am, and that is exactly the case in NM. Collectives would help rural area patients as well if we make it to where everyone has the right to grow, their plant count would then be transferred to the collective, and they will grow their plants for them. Thus further lowering the concerns of the blackmarket, California, Colorado, and other select rec states are the stem of our black market issue, not New Mexico PPL holders. I have spoken with several patients with PPLs and this is the consensus I have come up with.

This will be my similar argument that I will speak on when I am there on the 12th of July.

Finally I will discuss my concerns with the new LNPP plant count, which there is only one really. It has to do with the size of the plant being considered a "mature" plant. The rule imposed isn't consistent with when a plant is actually mature. 8 inches is sometimes the size of a non mature clone, and if i wanted to I could plant 10,000 7 inch plants, flower them, and they would never count against my plant count. This will happen if that rule is implemented, look at what craziness is going on just with the new definition of "qualified patient" this rule will only cause issues, and grey areas. If you simply use the real difference between a non mature or mature plant, then that count will be followed more. A plant is only mature, or flowering, when it is showing actual flowers, hairs, and it no longer grows fan leaves, the flowers will be very noticable, and there will be no way to cheat the system or find a grey area if we simply just use the real difference between a vegetating plant, and a flowering plant. This will also help the LNPPs do what the DoH has in their plan already without having to measure anything, a plant can be 10 feet tall and have no flowers, but there's no monetary value to it until it flowers or is harvested. Until then that plant is just another plant with only non psychoactive compounds, that does not happen until it is flowering.

I hope I was clear enough and didn't make too many grammatical errors, my dyslexia makes this complicated at times.

6/24/2019

[EXT] - comment, MCP, DOH

Thank you for your time, and I look forward to seeing and speaking with you all on July 12th.

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Chad Lozano

Secretary of New Mexico Medical Cannabis Patients advocacy alliance/


July 2, 2019

Attn: Senator Gerald Ortiz y Pino

Dear Governor Lujan Grisham,

Good evening, my name is Victoria Lopez. I am writing you because come Friday I will be unable to attend the meeting regarding Senate Bill 406 and the updates to the Medical Cannabis Program. I currently am a Peer Educator at one of our local medical cannabis dispensaries, but more importantly I am a New Mexican citizen

[REDACTED] obtained my associate's degree in human services and my bachelor's degree in social work. I have also done some work as a HIV Case Manager and most recently have found myself given the most amazing opportunity to work as a Peer Educator within the medical cannabis industry as I attempt pursuing my RN.

I am writing you today as a concerned citizen and a social advocate. I believe it is important to have a voice as we move forward and to be apart of the conversation as to how we interpret these laws. As a Peer Educator many people are coming to me, and well to us, and asking us what these changes to the law mean. I have one elderly patient that was already informed that if they failed their drug test the fact that they had their Medical Cannabis Card was irrelevant and they could potentially loose their jobs if randomly selected for a drug test. At that moment the patient stated that they were in so much pain that it didn't even matter if they lost their job. I found myself confused as what to say and how to address their concerns. The recent changes to the law indicate that there is some workplace protection but still it is so unclear and I would hate giving people false information. Especially when it comes to their livelihood.

[REDACTED]

Thank you so much for your time and all your hard work.

Sincerely,
Victoria Lopez

TO: Hearing Officer
Public Hearing on proposed Medical Cannabis Program rules changes
New Mexico Department of Health, scheduled 07/12/2019

FROM: Steven Jenison, MD, NRP
[REDACTED]

DATE: Monday 7/8/2019

RE: Medical Advisory Board - roles, responsibilities and authority

My name is Steven Jenison, MD, EMT-Paramedic. I am a retired public health physician and current volunteer Paramedic / Rescue Chief with the Dixon Volunteer Fire Department. I was the first Medical Director of the New Mexico Medical Cannabis Program with the New Mexico Department of Health from 2007 to 2010. After my retirement, I was appointed to the Medical Advisory Board to the NM Medical Cannabis Program and served as its Chair for years. I have had extensive involvement in the passage of the Lynn & Erin Compassionate Use Act, in the implementation and administration of the Program, and in advocacy for the Program and its participants to the present time. There are two administrative issues regarding the relationship between the Medical Advisory Board and the Department of Health that should be addressed in regulation:

- 1) The Secretary of Health should have a limited defined time within which to act upon recommendations of the Medical Advisory Board.

The statute states that the Secretary of Health must act upon recommendations made by the Medical Advisory Board, including recommendations to add new conditions to the list of those eligible for enrollment in the Program. Public hearings of the Medical Advisory Board at which petitions to consider the addition of new conditions are heard are held every 6 months. The Medical Advisory Board is required to submit a report to the Secretary of Health within 2 weeks of the hearing. On many occasions over the past 8 years, the Secretary of Health has not acted upon the recommendations until days before the next hearing (if then). This does not allow the public to submit an amended or new application for that condition within the time limits required for consideration at the next public hearing. This practice of the Department of Health has come to be viewed by many in the advocacy community as an abuse of administrative authority. A rule should be added that requires the Secretary of Health to formally act upon recommendations of the Medical Advisory Committee within 3 or 4 months of receiving the public hearing report.

- 2) The Department of Health should respect the statutory authority of the Medical Advisory Board to provide consultation on a) changes to patient enrollment eligibility; and, b) changes in allowed quantities and preparations of cannabis available to patients in the program.

Section 6, Paragraphs D and E, of the Lynn & Erin Compassionate Use Act state that the Medical Advisory Board shall: *D. issue recommendations concerning rules to be promulgated for the issuance of the registry identification cards; and, E. recommend quantities of cannabis that are necessary to constitute an adequate supply for qualified patients and primary caregivers.*

It is unfortunate that there have been occasions over the past 8 years when the Department of Health failed to adequately consult the Medical Advisory Board regarding changes in these areas. I recommend that clear language be added to the Rules that require the Department to consult the Medical Advisory Board regarding any changes to patient enrollment rules, quantities of cannabis that are allowed and over what time frame, and preparations of cannabis available to patients. The administrative process for obtaining this consultation should be clearly defined, and it should occur well before the Department publishes proposed rules changes - according to the intent of the statute.

[EXT] Petition to increase ppl count

ultimate pipe [REDACTED] >

Tue 7/9/2019 3:42 PM

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

Dear Medical Cannabis Board

On behalf of my [REDACTED], and being his official caregiver, we are officially requesting an increase in plant count. The reason for this increase on his plant count is because we can no longer afford to treat him [REDACTED]. Joseph Jr requires a daily regimen of 4 g of oil per day to keep his seizures at bay.

We have been pleading with DOH to increase his plant count for sometime now to no avail. I am officially requesting this plea to be on the agenda as an action item. I will be attending the next cannabis board meeting on July 12, 2019.

I also know that today, Tuesday July 9th is the deadline to submit my petition to the Board.

Respectfully submitted,

[REDACTED] r

[EXT] Public Comments on the July 12th Hearing

Jambox Band [REDACTED]

Tue 7/9/2019 10:35 AM

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

Home Cultivation of Cannabis Medicine

The need for a home grow option in the context of a Medical Cannabis Program is based on two important policy elements that compel it's inclusion in any admendment or bill.

1. The most important is the compassionate aspect that should be at the heart of the discussion. It's primary function (Home cultivation) should stand as a safety net for those that have already exhausted their wealth paying for medical hospitalizations, doctors, pharmaceuticals, treatments , diagnostics (x-rays, Chemo or Radiation Therapy, MRI's, PEP Scans, Blood draws..etc...etc...). For a vast majority of patients that have been battling any chronic disease process, it is a harsh reality, that poverty is a natural part of their suffering.This safety net of compassion will not use any tax dollars or government expenditure.

Home cultivation allows specific strains for patients that the dispensaries do not grow, that is only effective in any specific individual case.

Another consideration to be considered in the context of compassion is the vast distances for patients to travel to get to a dispensary. You have to add the cost of going and coming to the cost of your medicine.(gas being \$ 2.00 to \$ 3.00 per gallon)

Another consideration is the lack of affordable health insurance. If by good fortune you have medical insurance, it will not pay for Medical Cannabis, thus making it hard to pay medical dispensary prices, if you are living from paycheck to paycheck. Those who lack insurance coverage typically enjoy far-worse health status than their insured counterparts. ((Individuals in fair or poor health status who are significantly more likely than others to be uninsured for longer periods.))"

Home cultivation is something that cannot be bargained away, without great loss and harm to the Medical Cannabis Community.

<https://www.greenentrepreneur.com/article/293761>

In year 2016, medical cannabis users shopped every 10 days and spent \$136 per transaction.

The many challenges that patients have to endured should not include paying for medicine that they cannot afford in the dispensary model. Home cultivation gives them a affordable option to improve their quality of life by producing their own medicine with minimal cost to them.

Home cultivation offers hope and compassion.

That is why the majority of patients support home cultivation, not just for themselves, but embracing compassion for others.

2. In American society, in every aspect of our lives, there is multiple choices. There are choices of clothes, doctors, cars, airlines, hospitable , prescription, jobs...etc...etc which leads to many benefits.

Why not in the delivery or choice of medical cannabis consumption.

As we shall show , the large percentage, roughly 8 out 10 will choose dispensary grown cannabis. There will be a small percentage that are not financially challenged that will choose to grow there own, simply because they like horticulture, it appeals to them and because they have a choice, not because of any financial hardship.

Overview of States with Home Cultivation Rights

1. Alaska- At least 21 years of age..... Total 6 plants, with 3 flowering at one time

2. Arizona- 25 miles from a Dispensary..... 12 Plants, Licences to grow - Of the 167,107 patients, only 1,892 grow, which amounts to 1.13%\
3. California- At least 21 years of age..... Total 6 plants
4. Colorado- Any Adult..... Total 6 plants, with 3 flowering at one time
5. Hawaii- Any Adult..... Total 7 plants
6. District of Columbia- At least 21 years of age..... Total 6 plants, with 3 flowering at one time
7. Maine- At least 21 years of age..... Total 12 plants, with 3 flowering at one time
8. Massachusetts- At least 21 years of age..... Total 6 flowering, not visible to public
9. Michigan- 12 plants per registered medical patient
10. Nevada- 25 miles from Dispensary, 6 plants in private residence..... total 12 per household
11. Montana- 12 total immature and 4 flowering
12. New Mexico- 12 total immature and 4 flowering,..... 30 dollar Personal Production fee.
13. North Dakota- 8 Plants 40 miles from Dispensary
14. Oregon- 6 Plants per resident for Medical patients
15. Rhode Island- 12 plants in a indoor facility
16. Vermont- 7 seedlings and 2 flowering
17. Washington- registered Medical Patients 6 plants. A doctor can prescribe up to an additional 9 plants for a total of 15 plants.

Of the 17 states that have granted a home cultivation privilege, only two states really have instituted a way to monitor how many take advantage of this opportunity, that I could find statistics on, Arizona and New Mexico. New Mexico charges a modest application fee and your right is stamp on your medical cannabis card. Arizona charges no fee but on the application for your medical card you have to state if you intend to grow and meet the qualifications. If you do then it's marked on your card as well. From their statistics, from 1.13% to 13.2% have participated in this privilege.. Most prefer to buy dispensary cannabis.

It really is a win for everybody to have a home cultivation program. The dispensaries stay viable and you give substance and hope to a small percentage that desperately need the compassion of home cultivation.

Another reason is that dispensaries run out of product or have few choices that cannot possibly meet the demands or needs of all patients.

You the politician will win, because you will have reached out to those within the medical cannabis community, to compromise and come together to find a solution. Neither side will get all they want but the real upside is that we have worked together to find a solution, creating goodwill and respect.

In today's politics this will be something we can all be proud of.

<https://www.leafly.com/news/cannabis-101/home-cannabis-cultivation-laws-a-state-by->

Arthur Mayer

Safe Access New Mexico
Jason Barker

[REDACTED]

Wednesday, July 10th 2019

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

MCP.comment@state.nm.us



Introduction:

The Medical Cannabis Program Plant Count and Adequate Supply MUST be protected from and kept entirely separate from any future Recreational Cannabis law, and this should be written in the Rules in Regulations. A review of 15 medical cannabis producers menus shows that the medical cannabis program is not providing an adequate supply of cannabis derived CBD products for the over 80, 000 medical cannabis patients. This one day review of menus showed 919 Total THC Products to only 90 Total CBD Products available on that day. Another survey conducted by the Medical Cannabis Program exposed how 55% of producers said they have been unable to keep pace with patient demand for cannabis and related products. Doctors on the state's Medical Cannabis Advisory Board and the program Medical Director could also be taking the time, at least once quarterly, to visit dispensaries to see what products are available to the patient community.

Public Comment For:

Revisions to nonprofit producer licensure requirements, including cannabis plant limits, licensing fee requirements, and the specification of certain quarterly reporting requirements;

[NMAC 7.34.4 - Medical cannabis licensing requirements for producers, couriers, manufacturers and laboratories. <https://nmhealth.org/publication/view/rules/4987/>]

Cannabis Plant Limits:

Making revisions to the proposed licensing requirements for medical cannabis licensed producers with a plant count that sets a standard for the amount of cannabis CBD strains/plants to be grown per licensure requirement. Making revisions limiting use of the medical cannabis program LNPP's licensure and plant count for that of the medical cannabis program and only the medical cannabis program. That is the Purpose of the Act.

Proposed Revision:

A non-profit producer that operates a facility and, at any one time, is limited to a combined total of no greater than ~~[2,500]~~ 1,750 cannabis ~~[mature female plants, seedlings and mature male]~~ plants, with 17% (percent) of all cannabis plants grown being that of cannabis derived CBD plants; not including seedlings, and an inventory of usable cannabis and seeds that reflects current patient needs~~[, and that shall sell cannabis with a consistent unit price, without volume discounts or promotional sales based on the quantity purchased].~~ A non-profit producer may possess any quantity of seedlings, as defined in this rule. A non-profit producer shall not possess a quantity of cannabis ~~[either mature female plants or seedlings and mature male]~~ plants that exceeds the quantities authorized by their licensure and associated licensing fee. A licensed non-profit producer may sell and distribute usable cannabis to a person or entity authorized to possess and receive it. A licensed nonprofit producer may obtain plants, seeds and usable cannabis from other licensed non-profit producers. A licensed non-profit producer may only use the cannabis plant for the operations of the state's medical cannabis program and can only be used in that medical cannabis program.

Or

Making revisions to licensing requirements for medical cannabis licensed producers with a plant count for patients and producers properly structured and increased: Medical cannabis CBD strains at ratio of; 1.5 thc(or lower) : 1 cbd (or higher) being removed from patient and producer allowable plant count.

Survey:

A review of 15 medical cannabis producers menus shows that the medical cannabis program is not providing an adequate supply of cannabis derived CBD products for the

over 80, 000 medical cannabis patients. This one day review of menus showed 919 Total THC Products to 90 Total CBD Products available.

Each and every qualifying health condition for the medical cannabis program requires the use of cannabis derived CBD in one form or another.

LNPP Menus Review of THC and CBD Products

1. Cannaceutics (Bernalillo) <http://www.cannaceutics.org/> : Flower was 105 THC products and 5 CBD products; Extracts was 6 THC Products and 2 CBD Products; Edibles was 26 THC products and 8 CBD Products; Topicals was 3 THC products and 0 CBD products.
2. CG Corrigan (Bernalillo) <https://www.cgoodinc.com/> (DoH has wrong web address listed) : Flower was 11 THC Products and 1 CBD product; Extracts was 12 THC products and 1 CBD product; Edibles was 28 THC products and 0 CBD Products.
3. Everest Apothecary (Bernalillo) <https://everestnm.com/> : Flower was 5 THC products and 0 CBD products; Edibles was 9 THC products and 0 CBD products; Extracts was 9 THC products and 2 CBD products; Topicals was 1 THC product.
4. Ultra Health - NM Top Organics (Bernalillo) <https://ultrahealth.com> : Flower was 8 THC Products and 1 CBD product; Edibles was 9 THC products and 1 CBD product; Extracts was 4 THC products and 2 CBD products; Topicals was 1 THC product and 2 CBD products.
5. PurLife (Bernalillo) <https://www.purlifenm.com/> : Flower was 39 THC and 2 CBD products; Extracts was 24 THC products and 0 CBD Products; Edibles was 31 THC products and 0 CBD products.
6. New Mexicann Natural Medicine (Santa Fe) <https://www.newmexicann.com/> : 41 total THC products and 10 total CBD products.
7. Pecos Valley Production (Dona Ana) <https://pecosvalleyproduction.com/> (DoH has wrong website listed): 37 total THC products and 10 total CBD products.
8. MJ Express-O/PurLife (Dona Ana) <https://www.purlifenm.com/location/203-s-foch-st-t-or-c-nm-87901/> : 65 total THC products and Zero CBD products.
9. Verdes Foundation (Bernalillo) <https://www.verdesfoundation.org/> : Flower was 7 THC products and 3 CBD products; Edibles was 9 THC products and 4 CBD products; Extracts was 7 THC products and 7 CBD Products.
10. R. Greenleaf (Bernalillo) <https://rgreenleaf.com> : Flower was 17 THC products and 3 CBD products; Edibles was 19 THC products and 13 CBD products; Extracts was 24 THC products and 4 CBD products; Topicals was 4 THC products and 0 CBD products.

11. Southwest Wellness Center (Taos) <https://www.southwestwellnesscenter.com> : Flower was 9 THC products and 1 CBD product; Extracts was 13 THC products and 1 CBD product; Edibles was 12 products and 0 CBD products.
12. New Mexico Alternative Care (San Juan) <http://www.newmexicoalternativecare.com> : 56 Total THC products and 2 total CBD products.
13. Minerva Canna Group (Santa Fe) <https://minervacanna.com/> : 53 Total THC products and 2 total CBD products.
14. Sacred Garden (Dona Ana) <https://app.trybaker.com/shop/1738?provider=1738> : 67 Total THC products and 5 total CBD products.
15. Organtica (Bernalillo) <http://organtica.com/> : 45 total THC products and 7 total CBD products.

919 Total THC Products to 90 Total CBD Products

Source:

Medical Cannabis Licensed Non-Profit Producer List

<https://nmhealth.org/publication/view/general/2101/>

Article:

Surveys on medical pot detail New Mexico supply shortages | BY ASSOCIATED PRESS |

Published: Tuesday, May 14th, 2019 at 8:14am |

<https://www.abqjournal.com/1315387/provider-says-medical-cannabis-sales-trail-enrollment-growth.html>

- “In results obtained Tuesday, 55% of producers said they have been unable to keep pace with patient demand for marijuana and related products.”
- “Of the patients surveyed, about one in four said they were unable to purchase cannabis within the past 90 days because it was out of stock. Shortages were more pronounced in eastern New Mexico, with about four in 10 patients citing shortages.”

Why not use Hemp CBD?

Testing standards and safety protocols for Hemp derived CBD are non-existent in New Mexico and the serious lack of regulation poses a health risk for patients in the medical cannabis program.

- Hemp CBD Secret Shopper News Story with Lab Testing. On Monday, May 20th on the 6pm News broadcast, Anchor Royale Dá reported on her findings after purchasing Hemp CBD products from several retailers in New Mexico.

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<https://www.koat.com/article/mixed-bag-of-results-whats-really-in-your-cbd-products/27532208>

- Hemp CBD Secret Shopper News Story with Lab Testing (2nd One Conducted). Sunday, May 19th on the 10pm News broadcast, Investigative Reporter Nathan O'Neal reported on his findings after purchasing Hemp CBD products from several retailers in New Mexico.

<https://www.kob.com/new-mexico-news/4-investigates-cbd-industry-is-operating-in-the-dark/5359467/?cat=500>

Article: “Hemp Derived CBD vs. Cannabis Derived CBD”

“For many reasons, CBD-rich cannabis is a better source of CBD than industrial hemp. The only reason CBD derived from hemp is gaining any notoriety is as an attempted end-run around federal law. When cannabis prohibition is ended and cannabis is treated like any other agricultural product, CBD will be extracted from the best source of cannabidiol—CBD-rich cannabis. The need to derive CBD from industrial hemp will end.”

[<https://culturemagazine.com/hemp-derived-cbd-vs-cannabis-derived-cbd/>]

Conclusion:

“Adequate Supply” can be achieved, if it is approached that the supply must be available if Every Patient ALL went out and purchased on the same day. And plants counts should be based on plant canopy and square footage instead of counting individual plants.

For ensuring safe access to all areas of the state of New Mexico and proper administering of the Lynn and Erin Compassionate Use Act, by the New Mexico State Department of Health, this can be achieved by opening applications for producer licensure specific to rural expansion in the state and by providing a new plant count structure to provide adequate supply as follows;

First, not all medical cannabis plants are the same. The cannabis plant contains dozens and dozens of cannabinoids. The most well known cannabinoid for a long time has been tetrahydrocannabinol (THC), but as more scientific research is conducted involving cannabis and its ability to be used as a medicine, more and more people are learning about other cannabinoids, in particular cannabidiol (CBD). Some plants have THC and others produce CBD, THC has psychoactive properties that affect your brain and give you a ‘runner’s high’ while CBD does not.

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A plant count that is based on ratio of patients to serve with inclusion of empirical data for varying amounts cannabis plant material needed to manufacture different forms of medical cannabis medicine.

The Medical Cannabis Program Plant Count and Adequate Supply MUST be protected from and kept entirely separate from any future Recreational Cannabis law, and this should be written in the Rules in Regulations.

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 recreational cannabis 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. We caution policy makers against letting the debate surrounding legalization of cannabis for recreational use obscure the science and policy regarding the medical use of cannabis.

The State's Medical Cannabis Program expansion is now "Medically Necessary" and the State needs to allow the Department of Health to open the application process, the State needs to increase the Licensed Non Profit Producer plant count, add more licensed non-profit producers, in conjunction with other measures to ensure safe access to medicine and to be compliant with the law. Currently there is Less Than 1/3 of a cannabis plant per person in the medical cannabis program and 55% of Program LNPP's can not meet patient demand.

For ensuring safe access to all areas of the state of New Mexico and proper administering of the Lynn and Erin Compassionate Use Act, by the New Mexico State Department of Health can be achieved with "adequate supply" as follows:

Adequate supply of medical cannabis properly defined, structured, and increased.

1. Maximum quantity of usable cannabis increased to 425.243 grams per 3 months (2.5 ounces every two weeks).

2. Inclusion of empirical data for determining adequate supply for varying amounts cannabis plant material needed to manufacture different forms of medical cannabis medicine for proper dosage.

Example revisions to licensing requirements for the medical cannabis program LNPP's

1. Plant count for patients & producers properly structured and increased.
2. Cannabis CBD strains at ratio of; 1.5 thec (or lower) : 1 cbd (or higher) not counted against patient/caregiver or LNPP allowable plant count.
3. Clones and Cuttings provided to qualified patient / caregiver with a PPL by a LNPP's not counted against LNPP allowable plant count.
4. Plant Count that is based on ratio of patients to serve AND inclusion of empirical data for varying amounts cannabis plant material needed to manufacture different forms of medical cannabis medicine.
 - a. Patient / Caregiver PPL plant count increased to allow for 6 immature seedlings / clones / cuttings, 6 plants in vegetative stage, and 6 plants in flowering stage for a total of 18 cannabis plants.
 - b. The addition of Cooperative/Collective PPL's (Example Below)

Washington State Medical Cannabis Program Cooperatives (Established 7/2016)

Medical cannabis cooperatives allow up to four medical cannabis patients or their designated provider to join together to grow cannabis for the patients' personal use. Every member must be entered into the medical cannabis authorization database and have a medical cannabis recognition card. The total number of plants authorized for the participants may not exceed 60 plants.

Cooperatives must [register with the Washington State Liquor and Cannabis Board](#) (WSLCB) and follow all regulations.

Cooperative members may ONLY:

- Be in a cooperative if they have a valid medical cannabis recognition card.
- Form a four member cooperative.
- Participate in a cooperative if they are at least 21 years of age.
- Grow up to the total number of plants authorized, with a maximum of 60 plants.

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- Belong to one cooperative.
- Grow plants in the cooperative and not anywhere else.
- Use the cannabis and its products, and not sell or give away cannabis or cannabis products to anyone who is not in the cooperative.

A cooperative must be:

- Located at one of the member's homes or personal property.
- Limited to one cooperative per tax parcel.
- Enclosed by an 8-foot fence, if outdoors, and cannot easily be seen or smelled.

Learn more with Washington's Collectives: [A Patient's Guide to Medical Marijuana Cooperatives \(PDF\)](#).

“Section 2. PURPOSE OF ACT.—The purpose of the Lynn and Erin Compassionate Use Act is to allow the beneficial use of medical cannabis in a regulated system for alleviating symptoms caused by debilitating medical conditions and their medical treatments.”

The focus on cannabis policy in 2019 should be on the medical cannabis program expansion, education about medical cannabis and the program, and protecting the program like Governor Lujan Grisham promised.

Medical cannabis patients in New Mexico deserve safe access to their medicine at ALL schools before the state legalizes cannabis for other people to party with in a recreational market.

Medical cannabis patients in New Mexico deserve safe access to medical cannabis in hospitals and medical facilities, like little kids going through the horrors of cancer treatment at UNM, before the state legalizes recreational cannabis use.

Medical cannabis patients in New Mexico deserve safe access to medical cannabis in hospice care facilities and senior retirement communities before the state legalizes cannabis for other people to have fun with recreationally.

Our Military Veterans and First Responders deserve safe and equal access to medical cannabis before the state legalizes cannabis for other people to party with.

Any state educational institution of higher learning should have safe access to research medical cannabis and the state's medical cannabis program before legalization ruins that potential research.

All doctors and prescribing medical professionals in the State of New Mexico should have safe access to recommend the use of medical cannabis to their patients or patient's caregiver before recreational cannabis legalization.

The public comment provided above was derived from the following Sources:

1. Petition: Medical Treatment; Adequate Supply: LNPP Plant Count Increase | <http://lecuannmcpmcabpetitions.blogspot.com/2017/09/petition-lnpp-plant-count-increase.html> | By Safe Access New Mexico
2. Petition Introduction: Requesting for the Medical Treatment; Adequate Supply: Remove CBD from Plant Count | <http://lecuannmcpmcabpetitions.blogspot.com/2017/03/petition-introduction-requesting-for.html> | By Safe Access New Mexico
3. "Patient's Guide to CBD". The Patient's Guide to CBD is a comprehensive resource that covers a wide range of topics, including, available forms for use, what to look for on package labels, how to read a certificate of analysis, how CBD interacts with the endocannabinoid system, the current state of research, the compound's legal status, and how to talk to one's doctor about CBD. [<https://www.safeaccessnow.org/patientscbd>]
4. Americans For Safe Access [http://www.safeaccessnow.org/policy_shop]
5. Stith, S. S., Vigil, J. M., Brockelman, F., Keenan, K., & Hall, B. (2018). Patient-reported symptom relief following medical cannabis consumption. *Frontiers in Pharmacology*, 9, 96. [<https://www.frontiersin.org/articles/10.3389/fphar.2018.00916/full>]
6. Colorado Medical Marijuana Program [<https://www.colorado.gov/pacific/cdphe/medicalmarijuana>]
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July 11, 2019

Re: Comments on Proposed Rules

Dear Department of Health,

The purpose of this letter is to provide comment upon proposed amendments to various rule sections of the Department's Medical Cannabis Program rules at Parts 7.34.2, 7.34.3, and 7.34.4 NMAC. This letter is presented on behalf of 13 licensed cannabis producers: Ultra Health, PurLife, MJ Express-O, Sacred Garden, Natural Rx, Pecos Valley Production, Urban Wellness, Southwest Wellness, Shift, Sandia Botanicals, Kure, G&G Genetics, and Red Barn Growers, which represented over half (51.5%) of New Mexico's medical cannabis industry in the first quarter of 2019. The undersigned producers are a strong representation of the industry, including those who are legacy license holders, new license holders, small producers, medium producers, large producers, those located in the urban areas and rural locations.

7.34.4.7(Y) NMAC and 7.34.4.8(A)(2): Because of the Clone-Based Growing System, a Limitation of 1,750 Plants Greater than 8-Inches Is, in Operation, a Hard Limitation of 1,750 plants

Because of the actual methods of cannabis cultivation used by producers in New Mexico, a limitation of 1,750 plants greater than 8 inches is equivalent to an absolute limitation of 1,750 plants. The production methods of producers are explained further below, but the basic premise is that producers grow from clones, not seeds.

Clones are typically taken from the mothering plant in cuttings of approximately 6 inches. Therefore, the beginnings of the plant—the part that is actually placed in a growing receptacle—is already almost 8-inches high, which is the threshold for the plant limitation. The cultivation directors of the various producers agree that it takes less than seven *days* for a cannabis plant to grow from 6 inches to 8 inches in an indoor growing system. This growth occurs within the context of an indoor growth cycle of eight weeks. A cannabis plant will thus spend a very small proportion of its life being smaller than 8 inches.

An unlimited number of less-than-8-inches plants will thus provide only a negligible amount of growth capacity and will not meaningfully or appreciably add to the capacity of 1,750 plants. Although DOH may believe allowing an unlimited number of less-than-8-inches plants will significantly increase capacity, the cultivation practices described above refute that belief. The time that a cannabis plant is less-than-8-inches is, practically, *de minimis*. Therefore, adding an unlimited amount of plants less-than-8-inches is also only, practically speaking, a *de minimis* contribution to overall capacity.

Because the practical contribution to capacity of plants-less-than-8-inches is so minimal, the 1,750 figure is, in operative effect, a hard limitation of 1,750 plants. A limitation of 1,750 plants larger than eight inches is a limitation of 1,750 plants, period.

The Department of Health's internal study report, prepared by Freedman & Koski, viewed the plant count from the perspective of plants per year, broken down into three-month intervals. The internal study assumes an average of four "harvests" per year, or a turnover of four times per year (whether harvests are timed every quarter or are done on a rolling basis). This idea of turnover means that under DOH's reasoning, a plant count limitation for an entire year will be the plant count limitation times four. Therefore, under DOH's reasoning, the proposed rule "allows" the harvesting of 7,000 plants per producer per year (1,750 times four turnovers).

Additionally, it is apparent that DOH used the same idea of turnovers when evaluating the producer survey. The average number of plants reported by producers as sufficient was 3,016 (see Medical Cannabis Survey of Producers, page 6). It seems DOH divided this number by some kind of turnover factor to arrive at 1,750 plants. 3,016 divided by four is not 1,750, but the idea of some turnover coefficient does seem to drive the reduction of 3,016 to 1,750. It seems that DOH's logic was that producers believe *harvesting* and *actually cutting down* 3,016 plants per year would be sufficient.

However, DOH's assumption that the 3,016 number should be divided based on plant turnover is unsupported by the survey. It is true the survey asked how many plants "per year" producers believe would be sufficient. However, neither the survey question nor the survey results specify if producers understood "per year" to mean "actual number of plants cut down and harvested per year" or "number of plants kept in circulation." DOH is making an unsupported leap from the 3,000-plants-per-year figure to the 1,750 figure because it assumes, without support, that producers answered with the number of plants actually cut down, rather than the number of plants kept in circulation on a rolling basis.

Without more information on how the producers understood the question they were asked, DOH's turnover-factor reasoning is unsupported, arbitrary, and capricious.

Likewise, Freedman & Koski's practice of factoring in some turnover coefficient is not industry standard. Industry standard, as well as the statutory schemes of the majority of states with plant counts, do not assume or pretend that there is a standard turnover coefficient or constant. Rather, they measure plants on the number in constant circulation and re-circulation.

Additionally, DOH's analysis is overly simplistic because it is based on achieving only sufficiency, not optimization. DOH's analysis is based upon the program achieving the very bare minimum: patients being able to buy enough of the few products that are offered. DOH's analysis is not based upon the program achieving optimization and improvement, wherein patients are able to buy enough of the product *they actually need* at an equitable price. In fact, the stated purpose of the Lynn and Erin Compassionate Use Act is to provide for the beneficial use of medical cannabis.

“The statute provides for ‘beneficial use,’ and if patients cannot obtain cannabis from regulated sources in an amount which is actually beneficial, then the statute is an illusion. The specific mention of ‘beneficial use’ in the statute signals the statute intends to build a system where cannabis is not just available in a theoretical sense – as in, each patient gets access to one gram per month at \$100 per gram – but is available in an amount which can benefit patients,” Judge David K. Thomson wrote in his final order, attached as Exhibit A, over the plant count lawsuit which initiated the Emergency Rulemaking process over the plant count (D-101-CV-2016-01971, Final Order entered November 1, 2018, page 51). “DOH impermissibly reads into the statute its style of regulation that in fact impedes on its statutory mandate to ensure an adequate supply,” (D-101-CV-2016-01971, Final Order entered November 1, 2018, page 11).

The patient survey measured only what patients *are actually purchasing*, rather than what they would like to purchase, and rather than what they would purchase under better circumstances. The survey reported on purchasing patterns within a constrained marketplace, rather than the demand that would result in an open marketplace. Therefore, it is not a true reflection of demand—it is a reflection of patient demand in a market relatively devoid of choice.

The patient survey results stated “there are many customers who feel there is a need for a greater variety of products,” and patients indicated “there needs to be a greater variety and supply of products” (Survey Results of Patients, page 5). It is impossible for patients to report how much of a non-existent product they purchase, and this need for more variety will not be reflected in survey results reporting how much patients *actually purchase*. The Freedman & Koski recommendations do not take this need for more variety into account; it is based only on actual purchases, not the needed purchases that would take place in a marketplace with more variety and choice.

Page 10 of the patient survey response report lists “Number of grams of cannabis flower or bud purchased in a typical month.” The report also lists grams of concentrates, edibles, and topicals purchased. This is one of the blindspots of DOH’s analysis—it measures only what patients *can* purchase. It does not measure what patients *need to purchase* or *would purchase* in a marketplace responsive to their needs.

Another blindspot in DOH’s analysis is that it does not measure demand being lost to Colorado. The patient survey results indicate many patients are going to Colorado to purchase cannabis—and thereby risking criminal prosecution for carrying cannabis over state lines. Page 37 of the patient survey report recites comments from patients that “The prices are too high compared to Colorado. They also have a better selection and a better set up and customer service in Colorado” and “Colorado has better choice and better prices.”

The undersigned producers do not believe that any patient should have to risk carrying cannabis over state lines. The undersigned producers believe that New Mexico’s medical cannabis program should achieve optimization and sufficient functionality so that no New Mexico resident ever has to risk criminal prosecution for inter-state movement of cannabis.

The Freedman & Koski recommendations do not take into account this demand lost to Colorado, or that the New Mexico supply should strive to meet that demand. Again, the

Freedman & Koski recommendations are based upon actual purchases, rather than the silent and invisible demand driven by the current failures of the marketplace.

Furthermore, the patient survey reported that 48% of patients “say they would purchase more cannabis or cannabis derived products” in a 90-day period. Again, this extra demand is not reflected in the Freedman & Koski recommendations.

The distortion of the survey data is also seen by responses from both patients and producers about lack of variety, lack of specific products, and need for more specialization. The producer survey says 68% of producers “say patients request medical cannabis products that they do not produce, such as specific types of concentrates, strains, and vapes, as well as CBD products and inhalers” and 68% of producers “say there are certain medical cannabis products they would like to produce more of, but cannot (Producer Survey Report page 5).

The producers are caught in a Catch-22. They cannot provide the right mix of variety to satisfy patients because they do not have enough plants to figure out the proper mix of variety to satisfy patients. The undersigned producers very much desire to respond qualitatively to individual patient needs and requests, but they cannot do that when all of their capacity goes to satisfying quantity.

In order to achieve a quality program, a program where producers can provide variety, and a program that loses no demand to Colorado or to illegal sources, producers must have a buffer zone—a zone in which they can experiment with different products, a zone in which they can recapture those patients lost to Colorado, and a zone in which they can learn which products patients actually need. Producers cannot learn which products patients actually need until they create those products and put them on the shelf.

Additionally, the undersigned producers very much desire to improve the quality of their products, and quality will not be improved when all of supply is being used to meet the bare minimum of demand. In an ideal market, the producers would choose the best quality products to place on shelves and would destroy sub-optimal products. Overtime, this process would result in refinement of plants (choosing the best quality plants and re-cultivating those from clones). Overtime, as quality is improved, the quantity of plants needed might actually decrease. However, if producers cannot have the buffer zone to improve quality, there will not be the refinement that could optimize New Mexico’s medical cannabis program.

In short, the plant limitations mentioned in DOH’s analysis are overly simplistic and do not capture the latent or silent demand that obviously exists. DOH’s own survey reports indicate latent and silent demand in terms of variety, in terms of patients purchasing greater quantities, in terms of products not yet produced, and in terms of demand lost to Colorado and other non-program sources. Therefore, the figure in DOH’s analysis—that there is a demand of 543.46 plants-per-producer for a three-month period—cannot be considered an accurate measure of true demand.

The undersigned producers believe DOH should not simply attempt to achieve the bare minimum amount of sufficiency to provide gross quantity. Rather, DOH must attempt to achieve

optimization of the program, where producers are able to meet quantity measures and quality measures and provide the variety patients need. To achieve optimization, the plant count must be above the figures supplied in DOH's internal recommendations.

This is where DOH fails to understand or appreciate Dr. Kelly O'Donnell's demand model. The Freedman & Koski analysis seemed perplexed by Dr. O'Donnell's analysis, but Dr. O'Donnell takes into account the latent demand, invisible demand, and need for greater variety. This is why she recommends 5,000 mature plants. Furthermore, Dr. O'Donnell takes into account future patients, which Freedman & Koski do not. Dr. O'Donnell's report is attached here as Exhibit B.

Indeed, the exclusion of future patients from the Freedman & Koski analysis is another large blindspot. The Legislature recently added two qualifying conditions which will likely result in thousands of patients added to the program: autism and opioid use disorder. It is puzzling that DOH's analysis would not account for future growth.

It is also worth noting that although Freedman & Koski express puzzlement over Dr. O'Donnell's methods, no effort was made to contact Dr. O'Donnell for clarification. Instead of attempting to better understand Dr. O'Donnell's recommendations, the Department's consultants chose to draw erroneous conclusions from the misinterpretation of Dr. O'Donnell's data and attribute their inability to replicate her results to errors in her analysis rather than their own lack of diligence

The undersigned producers believe it is prudent to account for future growth sooner rather than later. To achieve optimization of the program *and to account for future patient growth*, the plant count must be above the figures supplied in DOH's internal recommendations. To not do so would be a dereliction of DOH's responsibility by statute to run, manage, and plan for the future of the program.

The judicial order that provoked the present rulemaking set out several requirements for a plant limitation. The final order stated, "Further any plant count, and certainly the 450 plant count, it may not be simply based on outdated and unrelated data in such a manner and means as to violate the Legislature's directive to provide an adequate supply" (D-101-CV-2016-01971, Final Order entered November 1, 2018, page 50). The order also stated, "the remedy would be to strike the 450 figure and remand to the Department for further proceedings to construct a quantity limitation which ensures producers can respond to patient demand" (page 53) and DOH "must make sure its decision is neither arbitrary nor capricious" (page 8).

If the plant limitation is, in operative reality, 1,750 plants, the limitation is not adequately based on recent and relevant data, and it is arbitrary and capricious. The data DOH has available to it are the survey results and Dr. O'Donnell's report and research. Those data support a figure of 3,000 plants for *current* patients in order to achieve optimization of the program, and 5,000 for the growth expected to occur in the coming years.

The producers propose a plant limitation based on flowering/non-flowering plants: 5,000 flowering and unlimited non-flowering plants (the difference between flowering and non-flowering will be explained further below).

Typically, in an indoor growth system, a plant will spend about half of its life in a non-flowering stage. Therefore, allowing unlimited numbers of non-flowering plants would provide considerable added growth capacity over the amount of mature plants. A limitation of 5,000 flowering plants would be much closer to the survey results and Dr. O'Donnell's report.

7.34.4.7(Y) NMAC and 7.34.4.8(A)(2): A Plant Limitation Based on "Seedlings" versus "Non-Seedlings" Is Irrational, Not Based on Evidence, Not Based on Actual Practice of Producers, Not Informed by Actual Agricultural Practices, Arbitrary, Capricious, and Contrary to Law

The proposed amendments change the definition of "seedling" and limit producers to possession/cultivation of "1,750 plants, not including seedlings." The definition of seedling is "a cannabis plant that has no flowers and that is less than eight (8) inches in height."

This definition of seedling and the plant limitations' distinction between "seedlings" and non-seedlings bears no rational relationship to the actual production practices of New Mexico Top Organics-Ultra Health and many other licensed producers. An understanding of actual cultivation practices is necessary to formulate a workable and appropriate plant limitation.

Most producers in New Mexico do not grow from seeds; they grow from clones. Attached as Exhibit C here are affidavits from producers attesting to their cultivation practices. Clones are cuttings made off of mature plants. Clones are used for a variety of reasons instead of seeds: 1) there is a shorter timespan from clone to maturation than there is from seed to maturation; 2) with clones, producers can ensure an exact genetic match to the mother plant, so the producer already knows the characteristics of the new plant; 3) there is no need to "sex" the new plant, because the clone will be the same sex as the mothering plant (and of course, producers are aiming for female plants, as the female plants are the ones that flower); 4) producers can ensure better quality control over a clone; with a seed, the producer must wait to find out the characteristics of the plant.

Growing from clones ensures the producer can constantly and consistently refine the cultivation of cannabis plants and cultivate the healthiest, most effective plants whose chemical characteristics are known. This quality control ultimately increases patient satisfaction, as it allows more targeted, scientifically-based medicine practices. Additionally, it decreases adverse events, as patients are not taking a chance on a plant strain they do not know.

Many patients ask for or are devoted to a particular "strain." Producers maintain strain integrity by using clones and cuttings. If seeds are used, the plant ceases to be of a particular "strain," because of genetic variation that happens during sexual reproduction. Therefore, clones are essential to patient satisfaction

Clones, when they are cut from the mothering plant, are already approximately 6 inches high. Cutting any less than that amount from the mothering plant may decrease the clone's potential for survival and growth.

DOH must understand that "mature" plant is not the same as a "non-seedling." Maturity is not tied to the size of the plant; it is tied to flowering stage of the plant. Indeed, NMAC 7.34.4.7(Z) defines a "mature female plant" as "a harvestable female cannabis plant that is flowering."

The producers agree that "mature" *is* roughly synonymous with "flowering." The producers also agree that mature/immature and flowering/non-flowering is a meaningful distinction that is informed by actual botanical/agriculture practices.

In contrast, seedling/non-seedling is not a meaningful distinction in the actual circumstances of cultivation of medical cannabis. The "seedling" phase as defined by DOH would last only a few days—from when the 6-inch clone is planted to when it passes the 8-inch threshold. The non-seedling phase (based on the 8-inch threshold) would last four to eight weeks. The more meaningful distinction is non-flowering/flowering, because the non-flowering phase lasts approximately five to eight weeks, while the flowering phase lasts approximately five to eight weeks.

This means that when DOH allows an unlimited number of seedlings, it does not appreciably extend producers' plant numbers, because a seedling will be a seedling for only a few days—the time between when a 6-inch clone is planted to when it surpasses the 8-inch threshold.

It appears DOH has differentiated between 8-inch "seedlings" and non-seedlings in the hopes of finding a practical way to effectively count plants. This is nonsensical because DOH has BioTrack and because producers must bar-code and track plants within the BioTrack system. Second, as a practical matter, plants are not separated by size, but by maturation and light phases. Cannabis plants are provoked into flowering through light deprivation. That is, in a greenhouse the producers will systematically provide the plants with certain amounts of light, and these amounts are specifically calibrated to provoke flowering.

The practical effect of this is that the plants ready to flower will be physically separated from the plants not yet ready to flower; these two categories of plants will be physically separated because they will receive different amounts of light each day. This means that as a practical matter, DOH's inspection duties would be equally served by differentiating between flowering/non-flowering as differentiating between less than 8 inches/greater than 8 inches.

The size of a plant would only be an effective tool to assist with inspection in outdoor growing areas, where the plants are not purposefully deprived of light and nature takes its course. However, only a nominal number of the 35 licensed producers have outdoor grows. Furthermore, when growing outdoors, all of the plants will be "seedlings" at the same time, and all will be mature at the same time.

The judicial order that provoked the present rulemaking set out several requirements for a plant limitation. The final order stated, “Further any plant count, and certainly the 450 plant count, it may not be simply based on outdated and unrelated data in such a manner and means as to violate the Legislature's directive to provide an adequate supply” (D-101-CV-2016-01971, Final Order entered November 1, 2018, page 50). The order also stated, “the remedy would be to strike the 450 figure and remand to the Department for further proceedings to construct a quantity limitation which ensures producers can respond to patient demand” (page 53) and DOH “must make sure its decision is neither arbitrary nor capricious” (page 8).

A plant count based upon a distinction between 8-inch seedlings and non-8-inch-seedlings is arbitrary and based on unrelated data, because it evidences no real understanding of the actual cultivation and agricultural practices of licensed producers.

An unlimited number of less-than-8-inch seedlings might provide an appreciable amount of flexibility if producers were growing from seeds and the plants took weeks to grow from seed to 8 inches. However, an unlimited number of less-than-8-inch seedlings does not provide an appreciable amount of flexibility in plant count because the timespan during which a cannabis clone will be less than 8 inches is less than ten *days* within a growth cycle of four to six *weeks*.

The differentiation between seedlings and non-seedlings is further shown to be arbitrary by the lack of specificity in the definition of “seedling.” The definition of seedling is that the plant is “less than eight (8) inches in height,” but this does not specify whether the measurement is made from soil to tip, from root to tip, or from ground to tip. This again shows DOH’s lack of familiarity with actual cultivation practices of producers.

The producers propose instead that DOH adopt a plant limitation that distinguishes between flowering plants and non-flowering plants. Producers should be allowed a certain number of flowering plants plus an unlimited number of non-flowering plants. The producers’ recommendation is 5,000 flowering plants, which will be addressed further below.

This proposal preserves DOH’s ability to effectively monitor the program and discourages any negative effects like diversion. The plant material that is subject to theft or diversion is primarily the flowers of the mature/flowering plant, and to a much lesser extent the leaves of a mature/flowering plant. This is because THC and CBD do not reach appreciable levels in the plant matter until the plant is in its flowering stage. Therefore, a non-flowering plant presents a vanishingly low susceptibility to diversion or theft.

7.34.4.8(B): The Provision for Increasing Plant Limitations for Individual Producers Is Arbitrary and Capricious and Encourages Further Arbitrary Decisions by DOH

7.34.4.8(B) NMAC states DOH “may increase the cannabis plant limitation for a licensed non-profit producer” by 500 plants if the producer “demonstrate[s] a need for the plant count increase to meet demand for their qualified patients.” This increase cannot be made until 2021.

This provision is arbitrary and unworkable. First, it gives authority for increases to “DOH;” it is unclear whether that means the Secretary, the Medical Cannabis Program director, or some unidentified DOH employee.

When regulatory authority of this kind is vested, it should be made clear who has that authority. The amorphous “DOH” is not enough; the authority should be vested clearly in the Secretary, the Medical Cannabis Program Director, or some kind of panel.

Perhaps a better source of authority would be the Medical Cannabis Advisory Board, which is a non-political group charged with ensuring the health—no pun intended—of the program and its patients. Assigning authority for an increase decision to a group, rather than a single bureaucrat, would better ensure the decision is based on science and data, rather than any other reasons.

Additionally, the regulation problematically indicates the decision will be based in part on “Any other information requested by the department.” Allowing DOH to request “any other information” renders the process entirely arbitrary, and it also sets a dangerous precedent of too much intrusion into producers’ internal business. Would this “any other information” include salaries of workers, revenue, profit margins, sales strategies, trade secrets?

Another problematic feature is that the department is allowed to make its determination based on whether the producers “inventory and average yield of usable cannabis is consistent with current averages from other licensed producers.” This provision encourages collusion between producers to achieve “consistency” with others.

This provision also discourages high performance and fails to reward high performers. If producers must keep their yields consistent as to each other in order to gain more plants, producers will have a perverse incentive to stagnate, rather than innovate. Collusion or coordination between producers should not be encouraged, because that coordination tends to discourage innovation and harm patients. An example is seen in the traditional pharmaceutical market, where different manufacturers of insulin increased prices in lockstep; this coordination is currently the subject of an anti-trust suit.

The undersigned producers, although united in these comments, believe that healthy competition between them will better serve patients than coordination and collusion.

The producers do not believe this arbitrary increase of 500 plants is workable at all; instead, the Department should simply commit itself to an annual or biannual survey of patients and producers and should commit itself to regular review and revision of the plant limitations.

7.34.3.9; Patient Purchase and Possession Limits Are Arbitrary and Outdated

The proposed rules leave unchanged the patient purchase/possession limitation. Under 7.34.3.9 NMAC, patients may possess no more than “230 units...equivalent to 230 grams, or approximately 8 ounces” within a three-month period. This section also effectively places a

purchase limitation on patients and producers, wherein a patient cannot purchase more than 230 grams per three-months.

This standard continues to be arbitrary and outdated. 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 BioTrack. 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.

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.

Additionally, there seems no relationship or logic between the possession/purchase limitation and the number of plants a patient may possess under a personal production license. The rule changes propose to allow patients *16 plants*, including four mature plants at a time. It is likely that four mature plants would create more than 8 ounces of usable cannabis. The prediction of personal growers achieving 8 ounces from four mature plants is highly conservative; even an unpracticed personal grower would be highly likely to glean more than two ounces per plant.

Thus, the rule changes create an inequity between patients who can grow their own plants and those patients who must rely solely on purchases from producers. The personal production

licensees could very well end up with more usable cannabis than consumers are allowed to purchase.

New Mexico's patient purchase limitations are much more restrictive than those of other states. As explained in the rulemaking petition previously submitted to DOH and reattached here as Exhibit D, other states are significantly more generous in purchase limitations.

What's more, the New Mexico Legislature passed a bill decriminalizing the possession of cannabis during this year's session. Adults in New Mexico who are in possession of up to one half ounce of cannabis are now only punishable by a \$50 fine. Thus, adults in New Mexico who are non-patients are allowed to possess one half ounce – a substantial portion of the Medical Cannabis Program's patient purchase limits – at any given time without criminal prosecution. In light of the passage of the decriminalization bill and the scant patient purchase limits in place today, it is as though non-patients in New Mexico have more possession rights for cannabis than those who are patients, who are going through the legal pathways to receive medical cannabis care.

The producers suggest a patient purchase/possession limitation that is not less than 2.5 ounces per 14-day period, which is equivalent 16 ounces per 90-day period.

7.34.4.7(RR): The Definition of Qualified Patient Is Now in Conflict With the Statute, and the Regulations Also Do Not Acknowledge Reciprocal Patients

The proposed rules leave unchanged the definition of “qualified patient,” even though that definition is now in conflict with the amendments to the Lynn and Erin Compassionate Use Act. As DOH knows, the Legislature in 2019 made changes to the Lynn and Erin Compassionate Use Act. The stated purpose of the changes was “to expand eligibility.” The Legislature also added a section stating “For the purpose of medical care, including an organ transplant, 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” (emphasis added).

This statement of purpose, the explicit normalization of medical cannabis as any other medical treatment, and the plain language of the Act, supports recognizing that the Act now allows non-residents to obtain registry identification cards.

The 2019 changes to the Act changed the definition of “qualified participant” from “a resident of New Mexico who has been diagnosed with a debilitating medical condition...” to “a person who has been diagnosed by a practitioner as having a debilitating medical condition...” NMSA 1978 § 26-2B-3(V) (2019). By this change, the statutory requirement that a “qualified patient” be a resident of New Mexico was abolished.

The law *also* now includes a definition for an entirely new type of participant in the Medical Cannabis Program (“MCP”), a “reciprocal participant.” A “reciprocal participant” is “an individual who holds proof of an authorization to participate in the medical cannabis program of

another state of the United States, the District of Columbia, a territory or commonwealth of the United States or a New Mexico Indian nation, tribe, or pueblo.” NMSA 1978 § 26-2B-3(W) (2019). This new category of participant is included in the law, presumably, because the law now required the New Mexico Department of Health (“NMDOH”) to promulgate rules by which participants in other states’ programs may participate in New Mexico’s MCP without the requirement of registering as a “qualified patient.”

Principles of statutory construction dictate that no part of a statute may be rendered superfluous (courts must interpret statutes “to avoid rendering the Legislature’s language superfluous.” *Baker v. Hedstrom*, 2013-NMSC-043, ¶ 24, 309 P.3d 1047); therefore, it is important that there are two different definitions for “qualified patient” and “reciprocal participant.”

That is, if there are two different terms, they must mean different things. This is seen in the definition of “registry identification card,” which is “a document that the department issues to a qualified patient...” but not to a “reciprocal participant.” This indicates a “reciprocal participant” is a separate category than “qualified patient.”

These definitions should be included in the regulations so that the regulations and statute are harmonized. Moreover, the definitions should be included to clarify that non-New-Mexico-residents may obtain registry identification cards and purchase from New Mexico dispensaries.

Now, by arguing that out-of-state residents should have medical cannabis privileges in New Mexico, the producers are **not** arguing for or encouraging cross-state trafficking. The Lynn and Erin Compassionate Use Act (“the Act”) and the entire body of all other laws of the State of New Mexico clearly, plainly, and obviously require that all consumption of cannabis pursuant to the Act occur exclusively within New Mexico, and that no inter-state movement of cannabis occur. The Act now includes a definition for “cannabis consumption area,” which is “an area within a licensed premises approved by the department where cannabis may be consumed that complies with rule as established by the department.” The Act also now states, “The department shall allow for the smoking, vaporizing and ingesting of cannabis products within a cannabis consumption area on the premises if: (1) access is restricted to qualified patients and their primary caregivers; (2) cannabis consumption is not visible from any public place or from outside the cannabis consumption area; and (3) qualified patients who consume cannabis on the premises have a designated driver or other means of transportation consistent with current law.”

This provision for cannabis consumption areas indicates intent to allow nonresidents to enter New Mexico, consume medical cannabis in a safe and monitored location, and then leave with a designated driver. While the consumption areas could also benefit New Mexico residents who lack a safe place to consume medical cannabis (such as those who live in federal housing), the consumption areas also clearly benefit nonresidents.

From a practical perspective, this provision appears designed to particularly cater to the needs of Texas residents. Both Arizona and Colorado have robust medical cannabis programs, and therefore Arizona and Colorado residents would not need to cross into New Mexico, consume cannabis, and cross back out. Arizona and Colorado residents could also obtain

reciprocity provisions, because Arizona and Colorado’s medical cannabis programs cover a broad range of medical conditions.

In contrast, Texas does not have a full medical cannabis program; it allows very limited use of CBD for people with epilepsy and a few other medical conditions (Texas recently did expand its program, but access is still limited to seven conditions and patients may only obtain CBD products).

Many New Mexico communities have robust and fruitful relationships with Texas towns across the border. Texas residents living in places like El Paso and Amarillo and Lubbock regularly cross into New Mexico to obtain other goods and services, and so residents of these areas could also cross into New Mexico, consume medical cannabis, and return home. This is *precisely* what the Legislature appears to expect to occur with both the reciprocity provision and the nonresident provision.

The Department need not, and should not, encourage people to transport cannabis over state lines. And indeed, licensed producers may choose to place their own limits on sales to out-of-state residents. Of course, it is the producers and the nonresidents who ultimately take the risks here, but they do so of their own volition.

In the over 10 years that New Mexico’s medical cannabis program has existed, no licensed producer has been the subject of any criminal or disciplinary action for diverting cannabis or contributing to criminal activities. In contrast, New Mexico’s licensed producers are professional, responsible, and focused every day on serving the needs of patients. The producers are capable of weighing potential costs and benefits and deciding whether to sell to nonresidents, and in what manner.

Likewise, it is the nonresident who takes the risk of entering New Mexico to consume medical cannabis. Certainly, DOH can use its resources to educate nonresidents about those potential risks and to advise nonresidents to think carefully about the choice.

The producers argue that the definitions section of the regulations should be amended to include the new, statutory definitions of “qualified patient” and “reciprocal participant.”

7.34.4.8(A)(1), 7.34.4.8(A)(1), 7.34.3.9: There Is No Logical Relationship Between Personal Production Limitations, Adequate Supply, and Producer Plant Limitation

There are three rules that, in a logically-designed system, should relate to each other. These three rules are the adequate supply, the personal production limitations, and the producer limitations.

The proposed rules change how many plants a personal production licensee can possess: four mature female plants plus twelve seedlings/male plants. The undersigned producers predict that a personal production licensee of average competence could obtain at least two ounces of usable cannabis per mature plant—two ounces of cannabis per mature plant is a very conservative prediction, even taking into account the skill level of personal licensees. Thus,

personal production licensees are effectively deemed to have “enough” cannabis at 8 ounces per harvest.

This is the same number in the adequate supply rule, 7.34.3.9, which limits possession and purchase to 8 ounces every three months.

If DOH’s rules are consistent that personal production licensees have “enough” cannabis at 8 ounces per harvest, and that all patients have an adequate supply at 8 ounces per 90 days, then one would expect the producer plant count to be somehow based on that same number: 8 ounces per patient per 90 days.

However, there is no evidence whatsoever that the producer plant limitation is based upon the 8 ounces per 90 days per patient figure. If the producer plant limitation was based upon the 8 ounces per 900 days per patient figure, then one would expect some reference to average yields expected of producers, but there is no such reference.

It is nonsensical for DOH to define—twice—what an adequate supply is for patients, and yet have the producer limitation bear no relation to the adequate supply figure.

Furthermore, when defined by plants instead of ounces, the lack of logic is even more apparent. The personal production limitation of four mature plants indicates that DOH believes four mature plants will bear enough usable cannabis for one patient during the particular duration of a harvest cycle.

However, that logic is not extended to the producer limitation. If four mature plants is “enough” per patient per a 90-day harvest cycle, then the ultimate plant limitation for producers should be a derivation of 4 plants multiplied by the number of patients in the program. The 90-day period does not exactly match with a typical sixteen-week indoor grow cycle, but they are somewhat in the same time range.

Currently, the program has more than 70,000 patients, not even counting those who will enter the program now that autism and opioid use disorders are qualifying conditions. 70,000 patients times 4 mature plants equals 280,000 mature plants per 12 weeks—nowhere near the 61,250 plants allotted in total to 35 producers who grow on a sixteen-week cycle.

In essence, DOH is saying one thing in one part of the regulations—that 4 mature plants is an adequate supply of cannabis for a personal production licensee—and then entirely ignoring that thing in another part of the regulations.

Plant limitations between producers and personal production licensees should, logically, be based on the same universe of data and same universe of assumptions and presumptions. It is true that commercial producers would likely achieve a higher yield-per-plant, but DOH has shown no data and provided no explanation that would explain the discrepancy between 4-mature-plants per patient in one section and 1,750 plants for producers in another section.

The producers argue that producer plant limitations should be based on the same 4-mature-plants-per-patient figure that the personal production license limitation is based on.

7.34.4.8(W): the Fee Schedule Is Exorbitant, Will Harm Small Businesses, Will Drive Up Patient Prices, and Is an Unconstitutional Tax

7.34.4.8(W) sets out the fee schedule for the operation of licensed producers. It states that producers shall submit a “non-refundable license fee...of: \$40,000 for the first 500 cannabis plants...\$5,000 for each additional increment of 50 cannabis plants above 500 and up to a collective total of 1,000 cannabis plants; and \$6,000 for each additional increment of 50 cannabis plants above 1,000.”

These fees are exorbitant and will harm small businesses. Additionally, they are so high as to constitute an unconstitutional tax. The high fees will also drive up prices for patients.

The new fee schedule begins at \$40,000 per year for 500 plants. The fee would be \$90,000 per year for 1,000 plants, and \$180,000 for 1,750 plants. These fees are a 11.1% increase over current fees for the same number of plants. It is not apparent from the proposed rules why DOH needs an increase of 11% to manage the program. DOH has not indicated any plans to license more producers, and it has again proposed a fixed plant limitation. It is not apparent what increased regulatory burdens would justify the increase in licensure fees.

DOH must view these numbers in the context of producers’ tax situation. Producers cannot take the same tax deductions that virtually all other small businesses take. Primarily, producers cannot deduct their expenses from federal income taxation, because of the Internal Revenue Code’s 280(E) provision. Currently, New Mexico also disallows producers from taking standard expense deductions from state income tax, although that ruling by the Department of Taxation and Revenue is under legal challenge. Producers are thus subject to very heavy income taxation.

Additionally, producers are not currently allowed to take the Gross Receipts Tax exemption for prescription drug sales, although that ruling is also under legal challenge.

The revenue of producers may appear very high, but this revenue is subject to heavy tax. The lack of tax deductions and exemptions somewhat distorts the perception of cannabis producers’ revenues and profits. While revenues may appear high, the profit margins of producers are far, far smaller.

If producers have to pay these very high licensing fees, they will have to pass the fees on to consumers. One of the issues that arose quite prominently in case D-101-CV-2016-01971 was customers being driven to the black market because of price. Many patients are on fixed incomes or lower incomes, and if producers cannot offer products at an affordable price, patients will go to the black market, and then the very purpose of the Compassionate Use Act will again be stymied. Producers must be encouraged and incentivized to lower prices and to maintain prices where patients can meaningfully afford product.

Furthermore, the \$40,000 beginning fee will simply price smaller producers out of the market. Additionally, if DOH plans to license new producers, the \$40,000 will be a very significant barrier to entry. New entrants into the market already face restricted access to capital and enormous startup costs (land, equipment, employees), and the \$40,000 entrance fee is another barrier.

Furthermore, while DOH has labeled the licensing fees as “fees,” they cross the line into unconstitutional taxes. Only the Legislature may levy a tax, and because of this separation-of-powers principle, courts closely watch when fees become effective taxes.

“Generally, a ‘fee’ is a charge intended to defray, in whole or in part, the expense of regulating or providing a service, benefit or privilege.” *New Mexico Mining Ass’n v. New Mexico Mining Comm’n*, 1996-NMCA-098, ¶ 22. A “regulatory fee must not exceed the amount reasonably necessary to cover the costs of performing or regulating the matter in question.” *Id.* at ¶ 23. If the fee exceeds the amount reasonably necessary to cover the costs of regulation, then it has effectively become a “tax.”

Theoretically, the lowest possible amount DOH could collect from the fees is \$1.4 million (\$40,000 times 35 producers). In actuality, DOH has previously collected approximately \$2.9 million per year in licensing fees, and this figure is unlikely to decrease.

To make this a permissible “fee” rather than an impermissible “tax,” DOH would have to show that its costs of regulating the Medical Cannabis Program are more than \$3 million per year. If this issue were legally challenged, the producers would seek evidence of DOH’s actual operational costs.

It is interesting to note the difference between DOH’s management of medical cannabis and the Department of Agriculture’s management of hemp. Hemp growers must pay an application fee of either 1) \$750 plus 75 cents for each square foot of indoor growing area; or 2) \$650 plus \$4 of outdoor growing area. The Agriculture Department also employs trained and specialized horticulturalists who will physically inspect hemp growing areas to ensure the plants do not contain unlawful concentrations of THC. There is no limitation on the number of hemp growers.

In contrast, DOH’s primary costs are staff, software licensing/support, and data management. DOH employs no specialized staff needed to make inspections, and DOH limits the number of producers.

The producers propose the following alternative fee schedule: a base of \$30,000 per year and no more than \$100,000 per year for any number of plants.

7.34.4.23(B)(3): The Quarterly Report Requirements Are Onerous and Bear No Relationship to Producer Practice

7.34.4.23(B)(3) now requires producers to submit reports on a quarterly basis, and those reports must contain 22 separate pieces of information. By regulation, DOH is now requiring a very detailed quarterly report from producers, with a significant number of pieces of information.

While the producers agree that DOH should collect data and should be informed by data in making decisions, many of the reporting requirements are redundant. Producers already enter an astonishing amount of information into BioTrack, but the regulation makes it appear that DOH has not yet obtained the ability to pull that information from BioTrack.

It is the producers' understanding that DOH has access to all information in BioTrack, and therefore the producers cannot understand having to provide this information essentially twice. The pieces of information that should be included in a quarterly report should match categories in BioTrack, or a BioTrack report/spreadsheet should be acceptable in lieu of a quarterly report.

Preparing quarterly reports in the manner suggested by this regulation would be onerous, would require significant employee time, and would further drive up consumer prices.

The Proposed Regulations Do Not Have a License Fee Provision for Manufacturers

Here, the comment is not on the regulations are proposing, but what is missing from the proposed regulations. Generally speaking, the regulations treat producers inequitably as compared to manufacturers.

The principle example of this is in the licensing fees. Producers are now expected to pay \$40,000 as a base, \$90,000 for 1,000 plants, and up to \$180,000, and yet manufacturers still have no listed licensing fee—they only have a nominal application fee.

The 2019 changes to the Lynn and Erin Compassionate Use Act do require DOH to promulgate rules setting licensing fees for manufacturers as well as producers. A new statutory section states, “by December 20, 2019, the secretary of health shall adopt and promulgate rules to establish fees for licenses for cannabis producers, cannabis manufacturers, cannabis couriers...”

It is unfortunate that DOH did not think to promulgate these regulations now, in this round of regulations. The statute now treats manufacturers as another class of licensee, and fees should be charged commensurate with that status.

7.34.4.7(FF) and 7.34.4.8(A)(2): Producers Do Not Have to Be Non-Profit

7.34.4.7(FF) NMAC proposes to add the definition “non-profit producer,” which is defined as “a New Mexico corporation that has been designated as a non-profit corporation by the New Mexico Secretary of State, that has been licensed by the department to produce medical cannabis in the state of New Mexico.” 7.34.4.8(A)(2) states DOH may license “a non-profit producer.”

The requirement that cannabis producers be non-profit corporations is inconsistent with the statutory language. In 2019, NMSA § 26-2B-3 was amended to add the terms “cannabis producer” and “licensed cannabis producer.” However, the Compassionate Use Act has never and still does not say “non-profit” anywhere. The statute has never and still does not require producers to be non-profit corporations. There is no statutory support for DOH’s requirement that producers be non-profit.

Furthermore, there remains unequal treatment of producers as compared to manufacturers, couriers, and laboratories, none of which are required to be non-profit corporations. This distinction may violate equal protection principles. “Like its federal equivalent, [Article II, Section 18 of the New Mexico Constitution] is essentially a mandate that similarly situated individuals be treated alike, absent a sufficient reason to justify the disparate treatment.” *New Mexicans for Free Enterprise v. City of Santa Fe* 2006-NMCA-007, ¶ 46, 138 N.M. 785, quoting *Wagner v. AGW Consultants*, 2005-NMSC-016, ¶ 21, 137 N.M. 734. Where an ordinance does not “impact or involve fundamental rights or suspect classifications,” the standard to be applied is rational basis. *Id.* Under that standard, the “classification, in order to be legal, must be rational; it must be founded upon *real differences of situation or condition*, which bear a just and proper relation to the attempted classification, and reasonably justify a different rule.” *Id.* at ¶ 49, quoting *Burch v. Foy*, 62 N.M. 219, 224, 308 P.2d 199, 202 (1957) (italics in original).

The producers propose that 7.34.4.7(FF) NMAC be eliminated entirely, that all references to “non-profit” producer be eliminated from all regulations, and that a definition for “cannabis producer” be added that is in accordance with the recent amendments to the Lynn and Erin Compassionate Use Act, that is, a “cannabis producer” should be defined as “a person that is licensed by the department to possess, produce, dispense, distribute and manufacture cannabis and cannabis products wholesale or by direct sale to qualified patients and primary caregivers.”

7.34.4.7(FF): the Definition of Producer Is Not in Compliance With Statute

An additional problem with DOH’s proposed definition of “non-profit producer” is that it does not match the statute. The undersigned producers believe the regulations should match the statutory text so there is no mistake or disagreement between statute and regulations.

Additionally, the recently amended statute explicitly memorializes what activities a licensed producer may lawfully do, and it would be very helpful if DOH recognized those activities.

The Compassionate Use Act now defines “cannabis producer” as “a person that is licensed by the department to possess, produce, dispense, distribute and manufacture cannabis and cannabis products wholesale or by direct sale to qualified patients and primary caregivers.” This definition is crucial for DOH to acknowledge because it sets out all the activities which a producer may lawfully perform.

There is still ongoing confusion, disagreement, and miscommunication between producers and DOH over wholesale activity. Some producers have received communications

from DOH prohibiting wholesale transactions between producers or between producers and manufacturers. Likewise, some producers have received communications from DOH that seem to discourage or question a producers' right to manufacturer cannabis-derived products.

This rulemaking presents a chance to clarify these issues. The statutory amendment clearly allows producers to manufacturer cannabis products *and* distribute those products wholesale. Likewise, the producers can also dispense wholesale, presumably to other producers.

The producers believe a wholesale market of producer-producer and producer-manufacture transactions can only benefit patients. Producers have developed niches in both strains and in certain products. Manufacturers have also developed specializations. Additionally, producers do sometimes experience supply problems, as anyone dealing with an agricultural commodity will. Wholesale transactions ensure dispensary shelves do not go empty for the "regular" customers who do have customary dispensaries.

There is no good reason *not* to include the statutory definition in the regulation; it is simply good practice to ensure the regulations match the statutes. The producers suggest that the term "non-profit producer" be eliminated, and that a definition for "cannabis producer" be added that is in accordance with the recent amendments to the Lynn and Erin Compassionate Use Act, that is, a "cannabis producer" should be defined as "a person that is licensed by the department to possess, produce, dispense, distribute and manufacture cannabis and cannabis products wholesale or by direct sale to qualified patients and primary caregivers."

7.34.4.24: Disciplinary Actions and Fines Are Unauthorized, Unconstitutional, and Arbitrary

The proposed 7.34.4.24 sets out a new system of disciplinary actions and fines.

The producers agree with DOH that reform is needed regarding disciplinary processes. The producers also agree that whether a violation implicates public safety or not is a valid criterion to consider in fashioning disciplinary penalties. However, the disciplinary penalties proposed are unauthorized and unconstitutional.

First, the penalties are unauthorized. The regulation gives DOH the right to impose monetary penalties/fines of up to \$50,000, and the imposition of fines may occur without any kind of pre-deprivation judicial or quasi-judicial inquiry. The New Mexico Supreme Court has indicated that agencies need explicit statutory authority to impose fines and monetary penalties.

That ruling was made in *Marbob Energy Corp. v. New Mexico Oil and Conservation Com'n*, 2009-NMSC-013, 146 N.M. 24. There, the Oil Conservation Division had regulations that purported to give OCD the authority to assess fines and penalties on oil producers who violated the Oil and Gas Act. The Supreme Court invalidated the OCD regulation because the Oil and Gas Act itself gave authority to the Attorney General to assess fines and penalties. The Oil and Gas Act itself did not give the authority to the OCD to assess fines and penalties.

Here, the Lynn and Erin Compassionate Use Act does not authorize any body to fine producers or issue monetary penalties to producers. Importantly, the Supreme Court held in *Marbob* that the OCD did not have implicit authority to issue fines: “The Commission argues that the broad jurisdiction and authority given the Division in these sections to do whatever is reasonably necessary to enforce the Act ‘is a clear and explicit delegation of jurisdiction of penalty assessment cases.’ We disagree.”

If this issue is challenged in court, DOH will likely make this same argument: that it has implicit authority to issue fines because it has authority to regulate the program. In *Marbob*, that was not sufficient, which indicates it will not be sufficient in this context.

In light of *Marbob*, the Legislature recently amended the penalties provision of the Oil and Gas Act. DOH should review this new provision of the Oil and Gas Act, because it describes a fair process for dealing with violations by oil producers.

Under the new version of NMSA § 70-2-31, the Oil Conservation Division “may seek compliance and civil penalties” against violators by 1) issuing a notice of violation; 2) commencing a civil action in district court; 3) issuing a temporary cessation order (for no more than 30 days) in instances of public health/safety dangers. The “notice of violation” must be very detailed and must contain an opportunity to cure the violation. If the violation is not cured, OCD may “hold a hearing and determine whether the violation should be upheld and whether any sanctions, including civil penalties, shall be assessed.”

As to the amounts of penalties, NMSA § 70-2-31 limits the penalties to \$2,500 “per day of noncompliance” or, in the case of violations affecting public safety, \$10,000 per day. In no event can the penalty be more than \$200,000.

Of course, the \$200,000 figure is in the context of the oil and gas industry, where producers make tens of millions, if not billions, in revenue, and are afforded very generous tax treatment.

Even if DOH had the authority to issue penalties, its disciplinary system is incomplete and unfair. The system allows DOH to issue penalties without any pre-deprivation process, it does not provide for a notification and opportunity to cure, and it does not include a provision for commencing an action in district court.

The producers recommend that if DOH has authority to issue fines and penalties, DOH adopt a disciplinary structure like that in the revised Oil and Gas Act to ensure the fair treatment of producers

As to the amount of penalties possible, DOH has created excessive fines in violation of the Eighth Amendment. “The Eighth Amendment protects against excessive civil fines, including forfeitures.” *State ex rel. Foy v. Austin Capital Management*, 2015-NMSC-025, ¶ 49, quoting *Hudson v. United States*, 522 U.S. 93, 103 (1997).

“A fine is unconstitutionally excessive if (1) the payment to the government constitutes punishment for an offense, and (2) the payment is grossly disproportionate to the gravity of the defendant’s offense.” *U.S. v. Mackby*, 261 F.3d 821, 829 (9th Cir. 2001). “We have held that “a civil sanction that cannot fairly be said solely to serve a remedial purpose, but rather can only be explained as also serving either retributive or deterrent purposes, is punishment.” *Id.* at 830, quoting *Austin v. United States*, 509 U.S. 602, 610 (1993).

“In determining whether a civil sanction is punitive or remedial, ‘the court considers factors such as the language of the statute creating the sanction, the sanction’s purpose(s), the circumstances in which the sanction can be imposed, and the historical understanding of the sanction.’” *Id.*

Here, the payments of up to \$50,000 to DOH constitute punishment for an offense. That amount cannot be fairly said to solely serve a remedial purpose, but can only be explained as serving a retributive purpose.

Finally, the regulation allows a penalty of up to \$5,000 for “each other violation.” This is highly subject to abuse by DOH. Many producers are routinely cited for packaging violations, although many of these violations actually originate in packaging made by manufacturers. It would be excessively harsh to force producers to pay \$5,000 every time a packaging error occurs, when the packaging error is in many instances out of their control.

As stated above, the producers recommend a stepped approach like that taken by the Oil and Gas Act, where a producer is given a notification of the violation, allowed an opportunity to cure, and fined only if the violation is not cured.

7.34.3.8: DOH Cannot Require Medical Records from Prospective Patients; this Regulation Violates the State

With 7.34.3.8, DOH proposes to require additional information from prospective patients with certain qualifying conditions.

For arthritis, patients must submit “medical records that confirm the diagnosis.” For neuropathy, the patient must submit “medical records that confirm the objective presence of painful peripheral neuropathy.” For PTSD, the patient must submit “medical records that confirm a diagnosis of PTSD meeting the diagnostic criteria of the current diagnostic and statistical manual of mental disorders.”

For chronic pain, the patient must submit “objective proof of the etiology of the severe chronic pain” and a “practitioner familiar with the patient’s chronic pain shall provide written certification that the patient has an unremitting severe chronic pain condition.”

Producers appreciate that DOH must ensure the list of qualifying conditions is taken seriously, but its manner of doing so violates the Compassionate Use Act. The Compassionate Use Act, as amended in 2019, states at NMSA 1978 § 26-2B-7(B) that DOH “shall issue registry identification cards to a patient...who submit the following...a written certification.”

The Compassionate Use Act defines “written certification” as “a statement made on a department-approved form and signed by a patient’s practitioner that indicates, in the practitioner’s professional opinion, that the patient has a debilitating medical condition and the practitioner believes that the potential health benefits of the medical use of cannabis would likely outweigh the health risks for the patient.” NMSA 1978 § 26-2B-3.

Particularly, the amendments to the Compassionate Use Act crossed out and eliminated from the definition of “written certification” the phrase “in a patient’s medical records.”

Thus, under the statutory language of the Compassionate Use Act, DOH cannot require submission of medical records. If DOH wishes to ensure certain qualifying conditions are not overused, it must add additional questions on the certification form for a doctor to answer.

For example, the certification form could have a space labeled “explain the etiology of the severe pain” and “describe your familiarity with the patient’s chronic pain.”

The certification form could have a space with the particular components of the DSM definition of PTSD, and require the practitioner to check each one.

Although DOH can amend its form to ensure that the patient actually has the debilitating medical condition, DOH cannot require submission of medical records.

Furthermore, in *Kieve v. NMDOH*, D-101-CV-2014-00140, the Court ordered “As part of an initial application for a patient card, the Department may require from patients and their practitioners no more information than what is included in NMSA 1978 § 26-2B-3(H)” (final order entered April 29, 2015). In that case, the NMDOH attempted to impose upon patients requirements to obtain registry identification cards that went beyond the requirements listed in the Act. The Court disallowed NMDOH’s imposition of non-statutory requirements for cards and reminded NMDOH that it lacked the authority to go beyond the clear and plain meaning of the Act when considering the issuance of cards to qualified patients.

DOH’s proposal to require medical records is in clear violation of the clear statutory language and the *Kieve* case.

Conclusion

Thank you for the opportunity to submit these comments. The undersigned producers sincerely wish and hope DOH takes these comments seriously.

Undersigned producers' Proposed Version of Rules

Key:

- Single strikethrough: Eliminated by DOH
- Double strikethrough: Eliminated by Undersigned producers
- Underlined: Added by DOH
- Colored: Added by Undersigned producers

7.34.3.7 DEFINITIONS:

A. “Act” means the Lynn and Erin Compassionate Use Act, NMSA 1978, Sections 26-2B-1 through 26-2B-7.

B. “Adequate supply” means an amount of cannabis, derived solely from an intrastate source and in a form approved by the department, that is possessed by a qualified patient or collectively possessed by a qualified patient and the qualified patient’s primary caregiver, that is determined by the department to be no more than reasonably necessary to ensure the uninterrupted availability of cannabis for a period of three months or 90 consecutive calendar days.

C. “Administrative review committee” means an intra-department committee that reviews qualified patient or primary caregiver application denials, licensed producer denials made by the program manager, or the summary suspension of a producer’s license, in accordance with department rules. The administrative review committee shall consist of the chief medical officer of the department (or that’s person’s designee); a deputy secretary of the department (or that person’s designee), and the chief nursing officer of the department (or that person’s designee).

D. “Administrative withdrawal” means the procedure for the voluntary withdrawal of a qualified patient or primary caregiver from the medical cannabis program.

E. “Advisory board” means the medical cannabis advisory board consisting of ~~[eight]~~ nine practitioners ~~[representing the fields of neurology, pain management, medical oncology, psychiatry, infectious disease, family medicine, and gynecology]~~ knowledgeable about the medical use of cannabis, who are appointed by the secretary.

F. “Applicant” means any person applying for enrollment or re-enrollment in the medical cannabis program as a qualified patient, primary caregiver, or licensed producer.

G. “Approved laboratory” means a ~~[laboratory]~~ licensed cannabis testing facility as defined in the Lynn and Erin Compassionate Use Act, NMSA 1978, § 26-2B-3(I) that has been approved by the department specifically for the testing of cannabis, concentrates, and cannabis derived products.

H. “Batch” means, with regard to usable cannabis, a homogenous, identified quantity of cannabis no greater than five pounds that is 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.

I. “Cannabidiol (“CBD”)” is a cannabinoid and the primary non-psychoactive ingredient found in cannabis.

J. “Cannabis” means ~~[all parts of the plant, cannabis sativa, and cannabis indica, whether growing or not and the resin extracted from any part of the plant]~~ all parts of the plant Cannabis sativa L. containing a delta-9-tetrahydrocannabinol concentration of more than three-tenths percent on a dry weight basis, whether growing or not; the seeds of the plant; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture or preparation of the plant, its seeds or its resin; and (2) does not include the mature stalks of the plant; fiber produced from the stalks; oil or cake made from the seeds of the plant; any other compound, manufacture, salt, derivative, mixture or preparation of the mature stalks, fiber, oil or cake; the sterilized seed of the plant that is incapable of germination; the weight of any other ingredient combined with cannabis to prepare topical or oral administrations, food, drink or another product; or hemp.

K. “Cannabis-derived product” means a product, other than cannabis itself, which contains or is derived from cannabis, not including hemp.

L. “Cannabis producer” means a person that is licensed by the department to process, produce, dispense, distribute, and manufacture cannabis and cannabis products wholesale or by direct sale to qualified patients and primary caregivers.

M. “Cannabis product” means 1) a product that contains cannabis, including edible or topical products that may also contain other ingredients; and 2) does not include the weight of any other ingredient

combined with cannabis or cannabis extract to prepare topical or oral administrations, food, drink, or another product.

N. “Concentrated cannabis-derived product (“concentrate”) means a cannabis-derived product that is manufactured by a mechanical or chemical process that separates any cannabinoid from the cannabis plant, and that contains (or that is intended to contain at the time of sale or distribution) no less than thirty-percent (30%) THC by weight.

O. “Courier” means a person or entity that transports usable cannabis within the state of New Mexico from a ~~licensed non-profit~~ cannabis producer to a qualified patient or primary caregiver, to another ~~non-profit~~ cannabis producer, to an approved laboratory, or to an approved manufacturer.

P. “Debilitating medical condition” means:

- (1) cancer;
- (2) glaucoma;

(3) multiple sclerosis;
 (4) damage to the nervous tissue of the spinal cord, with objective neurological indication of intractable spasticity;
 (5) epilepsy;
 (6) positive status for human immunodeficiency virus or acquired immune deficiency syndrome;
 (7) admission into hospice care in accordance with rules promulgated by the department; [Ø]
 (8) amyotrophic lateral sclerosis;
 (9) Crohn’s disease;
 (10) hepatitis C infection;
 (11) Huntington’s disease;
 (12) inclusion body myositis;
 (13) inflammatory autoimmune-mediated arthritis;
 (14) intractable nausea or vomiting;
 (15) obstructive sleep apnea;
 (16) painful peripheral neuropathy;
 (17) Parkinson’s disease;
 (18) posttraumatic stress disorder;
 (19) severe chronic pain;
 (20) severe anorexia or cachexia;
 (21) spasmodic torticollis;
 (22) ulcerative colitis; or
 (23) ~~(8)~~ any other medical condition, medical treatment, or disease as approved by the department which results in pain, suffering, or debility for which there is credible evidence that medical use cannabis could be of benefit.

Q. “Department” means the department of health or its agent.

R. “Facility” means any building, space, or grounds licensed for the production, possession, testing, manufacturing, or distribution of cannabis, concentrates, or cannabis-derived products.

S. “Flowering plant” means a female cannabis plant that is, whether by natural or artificial agricultural means, exposed to light deprivation with the intention of provoking the emergence of flowers; and any female cannabis plant that has flowers.

T. “Intrastate” means existing or occurring within the state boundaries of New Mexico.

U. “Laboratory applicant” means a laboratory that seeks to become an approved laboratory, or that seeks renewal of approval as an approved laboratory, in accordance with this rule.

V. “License” means the document issued by the department granting the legal right to produce medical cannabis for a specified period of time.

W. “Licensed producer” means a person or entity licensed to produce medical cannabis.

X. “Licensure” means the process by which the department grants permission to an applicant to produce cannabis.

Y. “Lot” means an identified portion of a batch, that is uniform and that is intended to meet specifications for identity, strength, and composition; or, in the case of a cannabis-derived product or concentrate, an identified quantity produced in a specified period of time in a manner that is uniform and that is intended to meet specifications for identity, strength, and composition.

Z. “Male plant” means a male cannabis plant.

AA. “Manufacture” means to make or otherwise produce cannabis-derived product or concentrate.

BB. “Manufacturer” means a ~~business entity that manufactures cannabis derived product that has been approved for this purpose by the medical cannabis program~~ person that is licensed by the department to manufacture cannabis products; package, transport or courier cannabis products; have cannabis products tested by a cannabis testing facility; purchase, obtain, sell and transport cannabis products to other cannabis establishments; and prepare products for personal production license holders.

CC. “Mature female plant” means a harvestable female cannabis plant that is flowering.

AA. “Medical cannabis program” means the administrative body of the department charged with the management of the medical cannabis program and enforcement of program regulations, to include issuance of registry identification cards, licensing of producers, and regulation of manufacturing and distribution.

BB. “Medical cannabis program manager” means the administrator of the medical cannabis program who holds that title.

CC. “Medical director” means a medical practitioner designated by the department to determine whether the medical condition of an applicant qualifies as a debilitating medical condition eligible for enrollment in

the program, and to perform other duties.

DD. “**Medical provider certification for patient eligibility form**” means a written certification form provided by the medical cannabis program signed by a patient's practitioner that, in the practitioner's professional opinion, the patient has a debilitating medical condition as defined by the act or this part and would be anticipated to benefit from the use of cannabis.

EE. “**Minor**” means an individual less than 18 years of age.

DD. “**Non-flowering plant**” means a female cannabis plant that has not, whether by natural or artificial agricultural means, been exposed to light deprivation with the intention of provoking the emergence of flowers; and any female cannabis plant that does not have flowers.

~~**FF.** “**Non profit producer**” means a New Mexico corporation that has been designated as a non profit corporation by the New Mexico Secretary of State, that has been licensed by the department to produce medical cannabis in the state of New Mexico.~~

GG. ~~[**FF.**]~~ “**Paraphernalia**” means any equipment, product, or material of any kind that is primarily intended or designed for use in compounding, converting, processing, preparing, inhaling, or otherwise introducing cannabis or its derivatives into the human body.

HH. ~~[**GG.**]~~ “**Patient enrollment/re-enrollment form**” means the registry identification card application form for patient applicants provided by the medical cannabis program.

II. ~~[**HH.**]~~ “**Personal production license**” means a ~~[license issued to a qualified patient participating in the medical cannabis program, to permit the qualified patient to produce medical cannabis for the qualified patient's personal use, consistent with the requirements of department rule]~~ license issued to a qualified patient or to a qualified patient's primary caregiver participating in the medical cannabis program to permit the qualified patient or the qualified patient's primary caregiver to produce cannabis for the qualified patient's use at an address approved by the department.

JJ. ~~[**II.**]~~ “**Petitioner**” means any New Mexico resident or association of New Mexico residents petitioning the advisory board for the inclusion of a new medical condition, medical treatment, or disease to be added to the list of debilitating medical conditions that qualify for the use of cannabis.

KK. ~~[**JJ.**]~~ “**Plant**” means any cannabis plant, cutting, or clone that has roots or that is cultivated with the intention of growing roots.

LL. ~~[**KK.**]~~ “**Policy**” means a written statement of principles that guides and determines present and future decisions and actions of the licensed producer.

MM. ~~[**LL.**]~~ “**Practitioner**” means a person licensed in New Mexico to prescribe and administer drugs that are subject to the Controlled Substances Act, Sections 30-31-1 *et seq.*, NMSA 1978.

NN. ~~[**MM.**]~~ “**Primary caregiver**” means a resident of New Mexico who is at least 18 years of age and who has been designated by the qualified patient or their representative and the patient's practitioner as being necessary to take responsibility for managing the well-being of a qualified patient with respect to the medical use of cannabis pursuant to the provisions of the Lynn and Erin Compassionate Use Act, Section 26-2B-1 *et seq.*, NMSA 1978.

OO. ~~[**NN.**]~~ “**Primary caregiver application form**” means the registry identification card application form provided by the medical cannabis program.

PP. ~~[**OO.**]~~ “**Private entity**” means a private, ~~non profit~~ organization that applies to become or is licensed as a producer and distributor of cannabis, concentrates, or cannabis-derived products.

QQ. ~~[**PP.**]~~ “**Proficiency testing**” means testing conducted by the department or its agent to determine the ability of a laboratory applicant or approved laboratory to accurately identify presence, quantity, or other factors pertaining to a given analyte.

RR. ~~[**QQ.**]~~ “**Qualified patient**” means a person ~~a resident of New Mexico~~ who has been diagnosed by a practitioner as having a debilitating medical condition and has received **written certification and** a registry identification card ~~issued pursuant to the~~ **Lynn and Erin Compassionate Use Act on the basis of having been diagnosed, in person or via telemedicine, by a practitioner as having a debilitating medical condition; provided that a practitioner may only issue a written certification on the basis of an evaluation conducted via telemedicine if the practitioner has previously examined the patient in person.** ~~requirements of the act or department rules.~~

“Reciprocal patient” means an individual who holds proof of an authorization to participate in the medical cannabis program of another state of the United States, the District of Columbia, a territory or commonwealth of the United States or a New Mexico Indian nation, tribe, or pueblo.

SS. ~~[**RR.**]~~ “**Registry identification card**” means a document issued and owned by the department which identifies a qualified patient authorized to engage in the use of cannabis for a debilitating medical condition or a document issued by the department which identifies a primary caregiver authorized to engage in the intrastate possession and administration of cannabis for the sole use of the qualified patient.

TT. ~~[**SS.**]~~ “**Representative**” means an individual designated as the applicant's or petitioner's agent, guardian, surrogate, or other legally appointed or authorized health care decision maker.

UU. [~~TT.~~] “**Secretary**” means the secretary of the New Mexico department of health.
VV. [~~UU.~~] “**Secure grounds**” means a facility that provides a safe environment to avoid loss or theft.

WW. [~~VV.~~] “**Security alarm system**” means any device or series of devices capable of alerting law enforcement , including, but not limited to, a signal system interconnected with a radio frequency method such as cellular, private radio signals, or other mechanical or electronic device used to detect or report an emergency or unauthorized intrusion.

XX. [WW.] “Security policy” means the instruction manual or pamphlet adopted or developed by the licensed producer containing security policies, safety and security procedures, and personal safety and crime prevention techniques.

~~**YY. [XX.]** “Seedling” means a cannabis plant that has no flowers and that is less than eight (8) inches in height.~~

ZZ. [YY.] “Segregate” means to separate and withhold from use or sale batches, lots, cannabis, usable cannabis, or cannabis-derived products in order to first determine its suitability for use through testing by an approved laboratory.

AAA. [ZZ.] “THC” means tetrahydrocannabinol, a cannabinoid that is the primary psychoactive ingredient in cannabis.

BBB. [AAA.] “Technical evidence” means scientific, clinical, medical, or other specialized testimony, or evidence, but does not include legal argument, general comments, or statements of policy or position concerning matters at issue in the hearing.

CCC. “Telemedicine” means the use of telecommunications and information technology to provide clinical health care from a site apart from the site where the patient is located, in real time or asynchronously, including the use of interactive simultaneous audio and video or store-and-forward technology, or off-site patient monitoring and telecommunications in order to deliver health care services.

DDD. [BBB.] “Testing” means the process and procedures provided by an approved laboratory for testing of cannabis and cannabis derived products, consistent with provisions of this rule.

EEE. [CCC.] “Unit” means a quantity of usable cannabis, concentrate, or cannabis-derived product that is used in identifying the maximum supply that a qualified patient may possess for purposes of department rules.

FFF. [DDD.] “Usable cannabis” means the dried leaves and flowers of the female cannabis plant and cannabis-derived products, including concentrates, but does not include the seeds, stalks, or roots of the plant. [7.34.4.7 NMAC - Rp, 7.34.4.7 NMAC, 2/27/2015; A, 2/29/2016; A, xx/xx/2019]

7.34.3.7 QUALIFYING DEBILITATING MEDICAL CONDITIONS:

A. Statutorily-approved conditions: As of the date of promulgation of this rule, specific qualifying debilitating medical conditions, diseases, and treatments (“qualifying conditions”) identified in the Lynn and Erin Compassionate Use Act, Section 26-2B-3(B) NMSA 1978, include:

- (1) cancer;
- (2) glaucoma;
- (3) multiple sclerosis;
- (4) damage to the nervous tissue of the spinal cord, with objective neurological indication of intractable spasticity;
- (5) seizure disorder, including epilepsy;
- (6) positive status for human immunodeficiency virus or acquired immune deficiency syndrome; ~~[and]~~
- (7) admission into hospice care in accordance with rules promulgated by the department.
- (8) amyotrophic lateral sclerosis (Lou Gehrig’s disease);
- (9) Crohn’s disease;
- (10) hepatitis C infection;
- (11) Huntington’s disease;
- (12) inclusion body myositis;
- (13) inflammatory autoimmune-mediated arthritis: each individual applying to the program for enrollment shall submit his or her medical provider’s statement that confirms the diagnosis of inflammatory auto-immune mediated arthritis; ~~medical records that confirm the diagnosis of inflammatory autoimmune-mediated arthritis.~~
- (14) intractable nausea/vomiting;
- (15) obstructive sleep apnea;
- (16) painful peripheral neuropathy: application to the medical cannabis program shall be accompanied by a medical provider’s statement that confirms ~~medical records that confirm~~ the objective presence of painful peripheral neuropathy;
- (17) Parkinson’s disease;
- (18) post-traumatic stress disorder (PTSD): each individual applying to the program for enrollment shall ~~submit a medical provider’s statement that confirms~~ ~~medical records that confirm~~ a diagnosis of PTSD meeting the diagnostic criteria of the current diagnostic and statistical manual of mental disorders;
- (19) severe chronic pain;

(a) a statement regarding the objective proof of the etiology of the severe chronic pain shall be included in the application; and

(b) a practitioner familiar with the patient's chronic pain shall provide written certification that the patient has an unremitting severe chronic pain condition;

(20) severe anorexia/cachexia;

(21) spasmodic torticollis (cervical dystonia); and

(22) ulcerative colitis.

B. Department-approved conditions: The department finds that the following additional qualifying conditions result in pain, suffering, or debility for which there is credible evidence that the medical use of cannabis could be of benefit, through the alleviation of symptoms, and the department accordingly approves these conditions as qualifying debilitating medical conditions for the participation of a qualified patient or primary caregiver in the medical cannabis program. The department-approved conditions include:

(1) autism spectrum disorder;

(2) Friedreich's ataxia;

(3) Lewy body disease;

(4) spinal muscular atrophy

(5) Alzheimer's disease;

(6) opioid use disorder;

~~_____ (1) severe chronic pain;~~

~~_____ (a) objective proof of the etiology of the severe chronic pain shall be included in the application; and~~

~~_____ (b) a practitioner familiar with the patient's chronic pain shall provide written certification that the patient has an unremitting severe chronic pain condition;~~

~~_____ (2) painful peripheral neuropathy: application to the medical cannabis program shall be accompanied by medical records that confirm the objective presence of painful peripheral neuropathy;~~

~~_____ (3) intractable nausea/vomiting;~~

~~_____ (4) severe anorexia/cachexia;~~

~~_____ (5) hepatitis C infection [currently receiving antiviral treatment: the written certification shall attest:~~

~~_____ (a) that the hepatitis C infection is currently being treated with antiviral drugs; and~~

~~_____ (b) to the anticipated duration of the hepatitis C antiviral treatment.~~

~~_____ (6) Crohn's disease;~~

~~_____ (7) post traumatic stress disorder (PTSD): each individual applying to the program for enrollment shall submit medical records that confirm a diagnosis of PTSD meeting the diagnostic criteria of the current *diagnostic and statistical manual of mental disorders*;~~

~~_____ (8) inflammatory autoimmune-mediated arthritis: each individual applying to the program for enrollment shall submit medical records that confirm the diagnosis of inflammatory autoimmune-mediated arthritis;~~

~~_____ (9) amyotrophic lateral sclerosis (Lou Gehrig's disease);~~

~~_____ (10) inclusion body myositis;~~

~~_____ (11) spasmodic torticollis (cervical dystonia);~~

~~_____ (12) Parkinson's disease;~~

~~_____ (13) Huntington's disease;~~

~~_____ (14) ulcerative colitis; and~~

~~_____ (8)(15) such other conditions as the secretary may approve.~~

C. Additional application requirements: A patient shall submit with the patient's application a written certification from the patient's practitioner which shall attest:

(1) to the diagnosis of the medical condition;

(2) that the condition is debilitating; and

(3) that potential risks and benefits of the use of medical cannabis for the condition have been discussed with the patient, in accordance with this rule; ~~a patient who applies on the basis of having a department approved condition may also be required to satisfy additional eligibility criteria, as specified in this rule.~~

D. Annual submittal requirements: A qualified patient shall submit annually to the department, on a department-approved form, a statement from a practitioner indicating that:

(1) the practitioner has examined the qualified patient during the preceding twelve months;

(2) the qualified patient continues to have a debilitating medical condition; and

(3) the practitioner believes that the potential health benefits of the medical use of cannabis would likely outweigh the health risks for the qualified patient.

E. [D.] Modification or removal of department-approved conditions: The secretary may remove or modify a department-approved condition only if the secretary determines, on the basis of substantial credible medical and scientific evidence, and after an opportunity for review of the proposed removal or modification by the medical advisory board, that the use of cannabis by patients who have the approved condition would more likely than not result in substantial harm to the patients' health.

[7.34.3.8 NMAC - N, 2/27/2015; A, 2/29/2016; A, xx/xx/2019]

7.34.3.8 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 ~~230 total units~~ **16 ounces**. For purposes of department rules, this quantity is deemed an adequate supply. ~~(For ease of reference, 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.

B. Calculation of ~~units~~ ounces: ~~units~~ **for cannabis-derived products and concentrated cannabis-derived products, the weight and quantity of usable cannabis shall be calculated by the weight of cannabis plant material and/or cannabis oils present in the product. The weight of non-cannabis materials, including foods, in the product shall not be considered or calculated toward the total weight of usable cannabis.** ~~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. [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 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 number of units 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.

[7.34.3.9 NMAC - N, 2/27/2015; A, xx/xx/2019]

7.34.3.9 QUALIFIED PATIENT AND PRIMARY CAREGIVER REGISTRY IDENTIFICATION CARD APPLICATION REQUIREMENTS:

A. The department shall issue a registry identification card to an applicant for the purpose of participating in the medical cannabis program upon the written certification of the applicant's practitioner and supporting application documents. Certifications from certifying providers must be obtained within 90 calendar days prior to the expiration of the patient's registry identification card.

B. The department may require the submittal of a recent photograph from a patient applicant and primary caregiver applicant.

C. [Replacement card fee: A fifty dollar (\$50) payment is required for replacement of registry identification card.

D. [The following information shall be provided in (or as an attachment to) the participant enrollment form submitted to the department in order for a registry identification card to be obtained and processed. An attached original medical provider certification for patient eligibility form shall contain:

- (1) the name, address, and telephone number of the practitioner;
- (2) the practitioner's clinical licensure;
- (3) the patient applicant's name and date of birth;
- (4) the medical justification for the practitioner's certification of the patient's debilitating medical condition, which shall include but not be limited to a statement that, in the practitioner's professional opinion, the practitioner believes that the potential health benefits of the medical use of cannabis would likely outweigh health risks for the patient;

(5) an attestation that the practitioner's primary place of practice is located within the state of New Mexico;

- (6) the practitioner's signature and the date;
- (7) the name, address, and date of birth of the applicant;
- (8) the name, address, and telephone number of the applicant's practitioner;
- (9) a legible photocopy of the applicant's New Mexico driver's license or comparable state

of New Mexico [~~or federal~~] issued photo identification card verifying New Mexico residence;

- (10) documented parental consent, if applicable, to the applicant;
- (11) the applicant's debilitating medical condition;
- (12) the length of time the applicant has been under the care of the practitioner providing the medical provider certification for patient eligibility;
- (13) the applicant's signature and date; and
- (14) a signed consent for release of medical information related to the patient's debilitating medical condition, on a form provided by the medical cannabis program.

D. [E.] Qualified minor: The department shall issue a registry identification card to an applicant under the age of 18 for the purpose of participating in the medical cannabis program upon the medical provider certification for patient eligibility from the applicant's practitioner and supporting application documents required under this rule. The qualified minor parental consent form shall require the following information to be provided:

- (1) written documentation that the applicant's practitioner has explained the potential risks and benefits of the use of cannabis to both the applicant and parent or representative of the applicant; and
- (2) written consent of the applicant's parent or legal representative to:
 - (a) allow the applicant's use of cannabis and cannabis-derived products;
 - (b) serve as the applicant's primary caregiver; and
 - (c) control the acquisition of the cannabis, dosage, and the frequency of the use of cannabis and cannabis-derived products by the applicant.

E. [F.] Primary caregiver: The department shall issue a registry identification card to a primary caregiver applicant for the purpose of managing the well-being of up to four qualified patients pursuant to the requirements of this rule upon the completion and approval of the primary caregiver application form available from the medical cannabis program. In order for a registry identification card to be obtained and processed, the following information shall be submitted to the medical cannabis program:

- (1) New Mexico driver's license or comparable state of New Mexico [~~or federal~~] issued photo identification card verifying that the applicant is at least 18 years of age and is a resident of New Mexico;
- (2) written approval by each qualified patient, and written approval by at least one certifying practitioner for each qualified patient, authorizing the primary caregiver's responsibility for managing the well-being of the patient(s) with respect to the medical use of cannabis;
- (3) the name(s), address(es), telephone number(s), and date of birth(s) of the qualified patient(s);
- (4) the name, address, and telephone number of each qualified patient's practitioner;
- (5) the name, address, and telephone number of the applicant primary caregiver;
- (6) an attestation from the primary caregiver applicant that he or she is a resident of the state of New Mexico;
- (7) the applicant primary caregiver's signature and the date; and
- (8) documentation of completed nationwide and statewide background checks conducted within six months of the application submission date.

F. [G.] Primary caregiver application requirements: Criminal history screening requirements.

- (1) All primary caregiver applicants are required to consent to a nationwide and statewide department of public safety (DPS) criminal history screening background check. All applicable application fees associated with the nationwide and statewide criminal history screening background check shall be paid by the primary caregiver applicant.
- (2) Individuals convicted of a felony violation of Section 30-31-20, 30-31-21, or 30-31-22 NMSA 1978, or a violation of any equivalent out-of-state statute in any jurisdiction are prohibited from serving as a primary caregiver. If an applicant has been convicted of a felony violation of Section 30-31-1 *et seq.* NMSA 1978, other than Sections 30-31-20 through 30-31-22, and the final completion of the entirety of the associated sentence of such felony conviction has been less than three years from the date of the applicant's application as a primary caregiver, then the applicant is prohibited from being a primary caregiver. The applicant and qualified patient shall be notified of his or her disqualification from being a primary caregiver. If the applicant has been convicted of more than one felony violation of Section 30-31-1 *et seq.* NMSA 1978 or a violation of an equivalent out-of-state statute in any jurisdiction, the applicant and qualified patient shall be notified that the applicant is permanently prohibited from being a primary caregiver and cannot be issued a medical use cannabis registry identification card.

G. [H.] Primary caregiver requirements:

- (1) A primary caregiver applicant shall be a resident of New Mexico.
- (2) A qualified patient's primary caregiver shall be permitted to obtain and transport medical cannabis from a licensed ~~nonprofit~~ to the qualified patient.

(3) The primary caregiver of a qualified patient who holds a personal production license may assist the qualified patient to produce medical cannabis at the designated licensed location, identified on the personal production license. ~~[The primary caregiver may not independently produce medical cannabis.]~~

(4) A qualified patient shall only reimburse their primary caregiver for the cost of travel, supplies, or utilities associated with the possession of medical cannabis, or cannabis-derived products by the primary caregiver for the qualified patient. No other cost associated with the possession of medical cannabis, or cannabis-derived products by the primary caregiver for the qualified patient, including the cost of labor, shall be reimbursed or paid. All medical cannabis or cannabis-derived products possessed by a primary caregiver for a qualified patient are the property of the qualified patient.

(5) A qualified patient shall notify the medical cannabis program in the event that the qualified patient ceases to retain the services of a primary caregiver. A primary caregiver shall promptly dis-enroll from the medical cannabis program at the time that the primary caregiver's services are no longer used by a qualified patient in their care.

H. ~~[I.]~~ Certifying practitioner requirements:

(1) A patient may not be certified by a practitioner who is related to the patient within the second degree of consanguinity or the first degree of affinity, including a spouse, child, stepchild, parent, step-parent, sibling, grandparent, mother-in-law, father-in-law, son-in law, or daughter-in-law of the patient.

(2) A practitioner's primary place of practice must be located within the state of New Mexico in order for the practitioner to certify a patient's eligibility.

(3) In order to certify a patient's application, a practitioner must have an actual physician-client relationship with the applicant or qualified patient~~[,]~~. A practitioner ~~[and]~~ shall conduct an in-person physical or mental evaluation of the applicant or qualified patient prior to issuing a certification. A practitioner may only issue a written certification on the basis of an evaluation conducted via telemedicine if the practitioner has previously examined the patient in person.

(4) A practitioner may be prohibited from certifying patient applications for:

- (a) failure to comply with any provision of this rule;
- (b) falsification of any material or information submitted to the department;
- (c) threatening or harming an employee of a producer, a medical practitioner, a patient, or an employee of the department; or
- (d) any determination by the practitioner's licensing body that practitioner has engaged in unprofessional or dishonorable conduct.

I. ~~[J.]~~ Continuing education of certifying practitioners: The department encourages certifying practitioners to obtain at least two continuing medical education credit hours annually related to the medicinal use of cannabis.

[7.34.3.10 NMAC - Rp, 7.34.3.9 NMAC, 2/27/2015; A, xx/xx/2019]

7.34.3.10 REGISTRY IDENTIFICATION CARDS:

B. Department registry identification card: The department shall issue a registry identification card within five business days of approving an application. A registry identification card shall include the name, address, and date of birth of the qualified patient and primary caregiver (if any), the date of issuance and expiration, date of the registry identification card, and a code maintained by the program which identifies the qualified patient or primary caregiver. Unless renewed at an earlier date, suspended, or revoked, a registry identification card shall be valid for a period of ~~[one]~~ three years from the date of issuance and shall expire at midnight on the day indicated on the registry identification card as the expiration date. A registry identification card is the property of the department, and shall be returned to the department upon the disenrollment, suspension, or revocation of a qualified patient or primary caregiver, and upon a change of address, or change of a qualified patient's primary caregiver.

E. Registry identification card renewal application: Each registry identification card issued by the department is valid for ~~[one]~~ three years from the date of issuance. A qualified patient or primary caregiver shall apply for a registry identification card renewal no less than 30 calendar days prior to the expiration date of the existing registry identification card in order to prevent interruption of possession of a valid (unexpired) registry

identification card. Certifications from certifying providers must be obtained within 90 calendar days prior to ~~the expiration of the patient's registry identification card~~ the submission of the application.

H. Lost or stolen registry identification card: The qualified patient or primary caregiver shall report a lost or stolen registry identification card to the medical cannabis program within five business days after discovery. Upon notification and receipt of the *information change or replacement card* form provided by the medical cannabis program, ~~and remittance of the fifty dollar (\$50) replacement fee,~~ the medical cannabis program manager or designee shall issue a new registry identification card. The patient or primary caregiver shall verify the accuracy of all documentation in the most recent application. Unless documentation in the most recent application has changed, the qualified patient or primary caregiver shall not be required to submit a new application. [7.34.3.11 NMAC - Rp, 7.34.3.10 NMAC, 2/27/2015]

7.34.3.15 PROHIBITIONS, RESTRICTIONS AND LIMITATIONS ON THE USE OF CANNABIS BY QUALIFIED PATIENTS: Participation in the medical cannabis program by a qualified patient or primary caregiver does not relieve the qualified patient or primary caregiver from:

- A. criminal prosecution or civil penalties for activities not authorized in this rule and act;
- B. criminal prosecution or civil penalties for fraudulent representation to a law enforcement officer about the person's participation in the program to avoid arrest or prosecution;
- C. liability for damages or criminal prosecution arising out of the operation of a vehicle while under the influence of cannabis or cannabis-derived products; or
- D. criminal prosecution or civil penalty for possession, distribution, transfer, or use of cannabis or a cannabis-derived product:
 - ~~(1) in a school bus or public vehicle;~~
 - ~~(2) on school grounds or property;~~
 - ~~(1)(3)~~ in the workplace of the qualified patient's or primary caregiver's employment;
 - ~~(2)(4)~~ at a public park, recreation center, youth center, or other public place;
 - ~~(3)(5)~~ to a person not approved by the department pursuant to this rule;
 - ~~(4)(6)~~ outside New Mexico or attempts to obtain or transport cannabis, or cannabis-derived products from outside New Mexico; or
 - ~~(5)(7)~~ that exceeds the allotted amount of usable medical cannabis, or cannabis-derived products.

[7.34.3.15 NMAC - Rp, 7.34.3.13 NMAC, 2/27/2015; A, xx/xx/2019]

7.34.3.17 EXEMPTION FROM STATE CRIMINAL AND CIVIL PENALTIES FOR THE MEDICAL USE OF CANNABIS:

B. A qualified patient shall not be subject to arrest, prosecution, or penalty in any manner by the state of New Mexico or a political subdivision thereof for the possession of or the use of medical cannabis if the quantity of cannabis, concentrates, or cannabis-derived products does not exceed an adequate supply as defined by rule; provided that a qualified patient or the qualified patient's primary caregiver may collectively possess that qualified patient's harvest of cannabis.

[7.34.3.17 NMAC - Rp, 7.34.3.15 NMAC, 2/27/2015; A, xx/xx/2019]

7.34.3.19 DISPOSAL OF UNUSED CANNABIS: Unused cannabis, concentrate, or cannabis-derived product in the possession of a qualified patient or primary caregiver that is no longer needed for the patient's needs may be disposed of by transporting the unused portion to a state or local law enforcement office, or by destroying the unused cannabis. Transfer to a ~~qualified patient, primary caregiver, or~~ ~~nonprofit~~ entity is prohibited. [7.34.3.19 NMAC - Rp, 7.34.3.17 NMAC, 2/27/2015; A, xx/xx/2019]

Undersigned producers' Proposed Version of Rules

Key:

- Single strikethrough: Eliminated by DOH
- Double strikethrough: Eliminated by Undersigned producers
- Underlined: Added by DOH
- Colored: Added by Undersigned producers

7.34.4.7 DEFINITIONS:

A. “Act” means the Lynn and Erin Compassionate Use Act, NMSA 1978, Sections 26-2B-1 through 26-2B-7.

B. “Adequate supply” means an amount of cannabis, derived solely from an intrastate source and in a form approved by the department, that is possessed by a qualified patient or collectively possessed by a qualified patient and the qualified patient’s primary caregiver, that is determined by the department to be no more than reasonably necessary to ensure the uninterrupted availability of cannabis for a period of three months or 90 consecutive calendar days.

C. “Administrative review committee” means an intra-department committee that reviews qualified patient or primary caregiver application denials, licensed producer denials made by the program manager, or the summary suspension of a producer’s license, in accordance with department rules. The administrative review committee shall consist of the chief medical officer of the department (or that’s person’s designee); a deputy secretary of the department (or that person’s designee), and the chief nursing officer of the department (or that person’s designee).

D. “Administrative withdrawal” means the procedure for the voluntary withdrawal of a qualified patient or primary caregiver from the medical cannabis program.

E. “Advisory board” means the medical cannabis advisory board consisting of ~~eight~~ nine practitioners ~~[representing the fields of neurology, pain management, medical oncology, psychiatry, infectious disease, family medicine, and gynecology]~~ knowledgeable about the medical use of cannabis, who are appointed by the secretary.

F. “Applicant” means any person applying for enrollment or re-enrollment in the medical cannabis program as a qualified patient, primary caregiver, or licensed producer.

G. “Approved laboratory” means a ~~laboratory~~ licensed cannabis testing facility as defined in the Lynn and Erin Compassionate Use Act, NMSA 1978, § 26-2B-3(I) that has been approved by the department specifically for the testing of cannabis, concentrates, and cannabis derived products.

H. “Batch” means, with regard to usable cannabis, a homogenous, identified quantity of cannabis no greater than five pounds that is 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.

I. “Cannabidiol (“CBD”)” is a cannabinoid and the primary non-psychoactive ingredient found in cannabis.

J. “Cannabis” means ~~[all parts of the plant, cannabis sativa, and cannabis indica, whether growing or not and the resin extracted from any part of the plant]~~ all parts of the plant Cannabis sativa L. containing a delta-9-tetrahydrocannabinol concentration of more than three-tenths percent on a dry weight basis, whether growing or not; the seeds of the plant; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture or preparation of the plant, its seeds or its resin; and (2) does not include the mature stalks of the plant; fiber produced from the stalks; oil or cake made from the seeds of the plant; any other compound, manufacture, salt, derivative, mixture or preparation of the mature stalks, fiber, oil or cake; the sterilized seed of the plant that is incapable of germination; the weight of any other ingredient combined with cannabis to prepare topical or oral administrations, food, drink or another product; or hemp.

K. “Cannabis-derived product” means a product, other than cannabis itself, which contains or is derived from cannabis, not including hemp.

L. “Cannabis producer” means a person that is licensed by the department to process, produce, dispense, distribute, and manufacture cannabis and cannabis products wholesale or by direct sale to qualified patients and primary caregivers.

M. “Cannabis product” means 1) a product that contains cannabis, including edible or topical products that may also contain other ingredients; and 2) does not include the weight of any other ingredient

combined with cannabis or cannabis extract to prepare topical or oral administrations, food, drink, or another product.

N. “Concentrated cannabis-derived product (“concentrate”) means a cannabis-derived product that is manufactured by a mechanical or chemical process that separates any cannabinoid from the cannabis plant, and that contains (or that is intended to contain at the time of sale or distribution) no less than thirty-percent (30%) THC by weight.

O. “Courier” means a person or entity that transports usable cannabis within the state of New Mexico from a ~~licensed non-profit~~ cannabis producer to a qualified patient or primary caregiver, to another ~~non-profit~~ cannabis producer, to an approved laboratory, or to an approved manufacturer.

P. “Debilitating medical condition” means:

- (1) cancer;
- (2) glaucoma;

(3) multiple sclerosis;
 (4) damage to the nervous tissue of the spinal cord, with objective neurological indication of intractable spasticity;
 (5) epilepsy;
 (6) positive status for human immunodeficiency virus or acquired immune deficiency syndrome;
 (7) admission into hospice care in accordance with rules promulgated by the department; [Ø]
 (8) amyotrophic lateral sclerosis;
 (9) Crohn’s disease;
 (10) hepatitis C infection;
 (11) Huntington’s disease;
 (12) inclusion body myositis;
 (13) inflammatory autoimmune-mediated arthritis;
 (14) intractable nausea or vomiting;
 (15) obstructive sleep apnea;
 (16) painful peripheral neuropathy;
 (17) Parkinson’s disease;
 (18) posttraumatic stress disorder;
 (19) severe chronic pain;
 (20) severe anorexia or cachexia;
 (21) spasmodic torticollis;
 (22) ulcerative colitis; or
 (23) ~~(8)~~ any other medical condition, medical treatment, or disease as approved by the department which results in pain, suffering, or debility for which there is credible evidence that medical use cannabis could be of benefit.

Q. “**Department**” means the department of health or its agent.

R. “**Facility**” means any building, space, or grounds licensed for the production, possession, testing, manufacturing, or distribution of cannabis, concentrates, or cannabis-derived products.

S. “**Flowering plant**” means a female cannabis plant that is, whether by natural or artificial agricultural means, exposed to light deprivation with the intention of provoking the emergence of flowers; and any female cannabis plant that has flowers.

T. “**Intrastate**” means existing or occurring within the state boundaries of New Mexico.

U. “**Laboratory applicant**” means a laboratory that seeks to become an approved laboratory, or that seeks renewal of approval as an approved laboratory, in accordance with this rule.

V. “**License**” means the document issued by the department granting the legal right to produce medical cannabis for a specified period of time.

W. “**Licensed producer**” means a person or entity licensed to produce medical cannabis.

X. “**Licensure**” means the process by which the department grants permission to an applicant to produce cannabis.

Y. “**Lot**” means an identified portion of a batch, that is uniform and that is intended to meet specifications for identity, strength, and composition; or, in the case of a cannabis-derived product or concentrate, an identified quantity produced in a specified period of time in a manner that is uniform and that is intended to meet specifications for identity, strength, and composition.

Z. “**Male plant**” means a male cannabis plant.

AA. “**Manufacture**” means to make or otherwise produce cannabis-derived product or concentrate.

BB. “**Manufacturer**” means a ~~business entity that manufactures cannabis derived product that has been approved for this purpose by the medical cannabis program~~ person that is licensed by the department to manufacture cannabis products; package, transport or courier cannabis products; have cannabis products tested by a cannabis testing facility; purchase, obtain, sell and transport cannabis products to other cannabis establishments; and prepare products for personal production license holders.

CC. “**Mature female plant**” means a harvestable female cannabis plant that is flowering.

AA. “**Medical cannabis program**” means the administrative body of the department charged with the management of the medical cannabis program and enforcement of program regulations, to include issuance of registry identification cards, licensing of producers, and regulation of manufacturing and distribution.

BB. “**Medical cannabis program manager**” means the administrator of the medical cannabis program who holds that title.

CC. “**Medical director**” means a medical practitioner designated by the department to determine whether the medical condition of an applicant qualifies as a debilitating medical condition eligible for enrollment in

the program, and to perform other duties.

DD. “**Medical provider certification for patient eligibility form**” means a written certification form provided by the medical cannabis program signed by a patient's practitioner that, in the practitioner's professional opinion, the patient has a debilitating medical condition as defined by the act or this part and would be anticipated to benefit from the use of cannabis.

EE. “**Minor**” means an individual less than 18 years of age.

“**Non-flowering plant**” means a female cannabis plant that has not, whether by natural or artificial agricultural means, been exposed to light deprivation with the intention of provoking the emergence of flowers; and any female cannabis plant that does not have flowers.

~~**FF.** “**Non profit producer**” means a New Mexico corporation that has been designated as a non profit corporation by the New Mexico Secretary of State, that has been licensed by the department to produce medical cannabis in the state of New Mexico.~~

GG. [FF.] “**Paraphernalia**” means any equipment, product, or material of any kind that is primarily intended or designed for use in compounding, converting, processing, preparing, inhaling, or otherwise introducing cannabis or its derivatives into the human body.

HH. [GG.] “**Patient enrollment/re-enrollment form**” means the registry identification card application form for patient applicants provided by the medical cannabis program.

II. [HH.] “**Personal production license**” means a ~~[license issued to a qualified patient participating in the medical cannabis program, to permit the qualified patient to produce medical cannabis for the qualified patient's personal use, consistent with the requirements of department rule]~~ license issued to a qualified patient or to a qualified patient's primary caregiver participating in the medical cannabis program to permit the qualified patient or the qualified patient's primary caregiver to produce cannabis for the qualified patient's use at an address approved by the department.

JJ. [H.] “**Petitioner**” means any New Mexico resident or association of New Mexico residents petitioning the advisory board for the inclusion of a new medical condition, medical treatment, or disease to be added to the list of debilitating medical conditions that qualify for the use of cannabis.

KK. [JJ.] “**Plant**” means any cannabis plant, cutting, or clone that has roots or that is cultivated with the intention of growing roots.

LL. [KK.] “**Policy**” means a written statement of principles that guides and determines present and future decisions and actions of the licensed producer.

MM. [LL.] “**Practitioner**” means a person licensed in New Mexico to prescribe and administer drugs that are subject to the Controlled Substances Act, Sections 30-31-1 *et seq.*, NMSA 1978.

NN. [MM.] “**Primary caregiver**” means a resident of New Mexico who is at least 18 years of age and who has been designated by the qualified patient or their representative and the patient's practitioner as being necessary to take responsibility for managing the well-being of a qualified patient with respect to the medical use of cannabis pursuant to the provisions of the Lynn and Erin Compassionate Use Act, Section 26-2B-1 *et seq.*, NMSA 1978.

OO. [NN.] “**Primary caregiver application form**” means the registry identification card application form provided by the medical cannabis program.

PP. [OO.] “**Private entity**” means a private, ~~non profit~~ organization that applies to become or is licensed as a producer and distributor of cannabis, concentrates, or cannabis-derived products.

QQ. [PP.] “**Proficiency testing**” means testing conducted by the department or its agent to determine the ability of a laboratory applicant or approved laboratory to accurately identify presence, quantity, or other factors pertaining to a given analyte.

RR. [QQ.] “**Qualified patient**” means a person ~~a resident of New Mexico~~ who has been diagnosed by a practitioner as having a debilitating medical condition and has received **written certification and** a registry identification card ~~issued~~ pursuant to the **Lynn and Erin Compassionate Use Act on the basis of having been diagnosed, in person or via telemedicine, by a practitioner as having a debilitating medical condition; provided that a practitioner may only issue a written certification on the basis of an evaluation conducted via telemedicine if the practitioner has previously examined the patient in person.** ~~requirements of the act or department rules.~~

“**Reciprocal patient**” means an individual who holds proof of an authorization to participate in the medical cannabis program of another state of the United States, the District of Columbia, a territory or commonwealth of the United States or a New Mexico Indian nation, tribe, or pueblo.

SS. [RR.] “**Registry identification card**” means a document issued and owned by the department which identifies a qualified patient authorized to engage in the use of cannabis for a debilitating medical condition or a document issued by the department which identifies a primary caregiver authorized to engage in the intrastate possession and administration of cannabis for the sole use of the qualified patient.

TT. [SS.] “**Representative**” means an individual designated as the applicant's or petitioner's agent, guardian, surrogate, or other legally appointed or authorized health care decision maker.

UU. [~~TT.~~] “**Secretary**” means the secretary of the New Mexico department of health.
VV. [~~UU.~~] “**Secure grounds**” means a facility that provides a safe environment to avoid loss or theft.

WW. [~~VV.~~] “**Security alarm system**” means any device or series of devices capable of alerting law enforcement , including, but not limited to, a signal system interconnected with a radio frequency method such as cellular, private radio signals, or other mechanical or electronic device used to detect or report an emergency or unauthorized intrusion.

XX. [WW.] “Security policy” means the instruction manual or pamphlet adopted or developed by the licensed producer containing security policies, safety and security procedures, and personal safety and crime prevention techniques.

~~**YY. [XX.]** “Seedling” means a cannabis plant that has no flowers and that is less than eight (8) inches in height.~~

ZZ. [YY.] “Segregate” means to separate and withhold from use or sale batches, lots, cannabis, usable cannabis, or cannabis-derived products in order to first determine its suitability for use through testing by an approved laboratory.

AAA. [ZZ.] “THC” means tetrahydrocannabinol, a cannabinoid that is the primary psychoactive ingredient in cannabis.

BBB. [AAA.] “Technical evidence” means scientific, clinical, medical, or other specialized testimony, or evidence, but does not include legal argument, general comments, or statements of policy or position concerning matters at issue in the hearing.

CCC. “Telemedicine” means the use of telecommunications and information technology to provide clinical health care from a site apart from the site where the patient is located, in real time or asynchronously, including the use of interactive simultaneous audio and video or store-and-forward technology, or off-site patient monitoring and telecommunications in order to deliver health care services.

DDD. [BBB.] “Testing” means the process and procedures provided by an approved laboratory for testing of cannabis and cannabis derived products, consistent with provisions of this rule.

EEE. [CCC.] “Unit” means a quantity of usable cannabis, concentrate, or cannabis-derived product that is used in identifying the maximum supply that a qualified patient may possess for purposes of department rules.

FFF. [DDD.] “Usable cannabis” means the dried leaves and flowers of the female cannabis plant and cannabis-derived products, including concentrates, but does not include the seeds, stalks, or roots of the plant. [7.34.4.7 NMAC - Rp, 7.34.4.7 NMAC, 2/27/2015; A, 2/29/2016; A, xx/xx/2019]

7.34.4.8 PRODUCER LICENSING; GENERAL PROVISIONS:

A. The department may license two classes of producers:

(1) A qualified patient or primary caregiver who holds a valid personal production license. 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. The primary caregiver of a qualified patient who holds a personal production license may assist the qualified patient to produce medical cannabis at the designated licensed location that is identified on the personal production license[; the primary caregiver may not independently produce medical cannabis].

(2) A licensed cannabis producer that operates a facility and, at any one time, is limited to a combined total of no greater than ~~[2,500]~~ 5,000 flowering cannabis plants, an unlimited number of non-flowering plants, and an inventory of usable cannabis and seeds that reflects current patient needs. A licensed cannabis producer may possess any quantity of non-flowering plants, as defined in this rule. ~~1,750 cannabis [mature female plants, seedlings and mature male] plants, not including seedlings, and an inventory of usable cannabis and seeds that reflects current patient needs[, and that shall sell cannabis with a consistent unit price, without volume discounts or promotional sales based on the quantity purchased]. A non profit producer may possess any quantity of seedlings, as defined in this rule. A non-profit producer shall not possess a quantity of cannabis [either mature female plants or seedlings and mature male] plants that exceeds the quantities authorized by their licensure and associated licensing fee. A licensed non-profit producer may sell and distribute usable cannabis to a person or entity authorized to possess and receive it. A licensed non-profit producer may obtain plants, seeds and usable cannabis from other licensed non-profit producers.~~

B. Increase to cannabis non-profit producer plant limit: The department may increase the cannabis plant limitation for a licensed non-profit cannabis producer in accordance with the following:

(1) Effective ~~September 1, 2019~~ June 1, 2024, a cannabis non-profit producer may request an increase of up to 500 flowering plants that exceeds the total plants allowed in section 7.34.4.8(A)(2) NMAC at the time of renewal of its licensure period. In order to be considered for approval by the department, the non-profit producer shall demonstrate a need for the plant count increase to meet demand for their qualified patients. The non-profit producer shall provide the following information to the department to demonstrate the need for a plant count increase:

(a) Average yield of usable cannabis flower and trim produced by the non-profit cannabis producer from the past 12 months;

(b) Current reported inventory of cannabis and cannabis-derived products;

~~(c) Percentage of usable cannabis and cannabis-derived products that was sold to qualified patients, primary caregivers, or to another licensed producer or manufacturer; and~~

~~(d) Any other information requested by the department.~~

~~(2) The **Medical Advisory Board** department shall make a determination to approve or deny the ~~non-profit~~ cannabis producer's request to increase plant count based on the following factors:~~

~~(a) The ~~non-profit~~ licensed producer has sold at least 80% of its usable cannabis for the last 12 months it has operated;~~

~~(b) The ~~non-profit~~ licensed producer's current inventory and average yield of usable cannabis is consistent with current averages from other licensed producers;~~

~~(c) The number and severity of complaints and enforcement actions on the ~~non-profit~~ licensed producer;~~

~~(d) The information provided by producer is consistent with the quarterly reports or inventory tracking information it has provided to the department within the last 12 months;~~

~~(e) Supply and demand of medical cannabis throughout the state and in underserved geographical regions; and~~

~~(f) The completeness of information and data provided to the department.~~

~~(3) Effective ~~June 1, 2021~~ **September 1, 2019**, a **cannabis non-profit** producer may request an emergency increase once per year outside of their license renewal period, of up to 500 plants that exceeds the total plants allowed in section 7.34.4.8(A)(2), at any time. The **cannabis non-profit** producer shall demonstrate a need for the plant count increase to meet demand for their qualified patients, and shall submit to the department the information identified in section 7.34.4.8(B)(1). The **Medical Advisory Board** department shall only approve the request if the **cannabis non-profit** producer can demonstrate ~~by clear and convincing~~ evidence that it is not able to meet qualified patient demand for usable cannabis or cannabis-derived products with its current plant count or by obtaining usable cannabis or cannabis products from another licensed producer. The **cannabis non-profit** producer shall provide objective data about the current supply in the medical cannabis market to demonstrate these factors. The ~~department~~ **Medical Advisory Board** shall also consider the same factors in subdivision (b) when approving or denying this request.~~

~~(4) Any increase in plant count approved under this section shall be voided in the event of a transfer of the majority of ownership for a licensed producer, at which time the plant limit for the license shall revert to the limit allowed in paragraph (A)(2).~~

~~(5) The department is not required to approve a request for an increase to a ~~non-profit~~ producer's plant limit and retains sole discretion to grant or deny the request.~~

C. [B.] Biannual Reviews: The Department shall conduct biannual reviews of producer licensing to determine whether the existing limitations on numbers of plants is satisfying qualified patient demand, is resulting in equitable prices, and is achieving the goals of the Lynn and Erin Compassionate Use Act.

- (1) The review shall include a survey of cannabis producers and qualified patients regarding supply and demand, price, and functioning of the medical cannabis program.
- (2) The results of the review and the survey shall be made available to cannabis producers, qualified patients, and the members of the Medical Advisory Board.
- (3) The results of the review shall be discussed in an open meeting of the Medical Advisory Board within two months of the survey's publication.
- (4) The Medical Advisory Board shall have the authority to recommend changes in cannabis producers' plant possession limitations, personal production licensees' plant possession limitations, or patient purchase and possession limitations.
- (5) If the Medical Advisory Board recommends any changes to the rules and regulations governing the Medical Cannabis Program, the Department must engage in rulemaking and promulgate substitute rules for notice, comment, and adoption.

D. Limitation on distribution: A **cannabis** producer shall not knowingly sell or otherwise distribute usable cannabis to any person or entity that is not authorized to possess and receive the usable cannabis pursuant to department rules.

E. [C.] Processing of production applications:

(1) The issuance of an application is in no way a guarantee that the completed application will be accepted or that a license will be granted. Information provided by the applicant and used by the licensing authority for the licensing process shall be accurate and truthful. Any applicant that fails to participate in good faith or that falsifies information presented in the licensing process shall have its application denied by the department.

- (2) The number of licenses issued by the department to ~~non-profit~~ private entities, and the

determination of which ~~non-profit~~ entities shall be licensed, shall be determined at the discretion of the secretary, which determination shall constitute the final administrative decision of the department.

(3) A ~~non-profit~~ producer whose application for licensure is not approved shall not be entitled to further administrative review.

F. [D.] Factors considered: The secretary shall consider the overall health needs of qualified patients and the safety of the public in determining the number of licenses to be issued to ~~non-profit~~ private entities and shall further consider:

- (1) the sufficiency of the overall supply available to qualified patients statewide;
- (2) the service location of the applicant;
- (3) the applicant's production plan, including but not limited to the applicant's plan for the growth, cultivation, and harvesting of medical cannabis;
- (4) the applicant's sales and distribution plan, including but not limited to the applicant's plan for sale of medical cannabis, plan for delivery (if any) to qualified patients, and the forms of usable cannabis and cannabis-derived products to be sold or distributed;
- (5) the applicant's skill and knowledge of horticulture and cannabis production technology, as well as the applicant's knowledge of current good manufacturing practice in manufacturing, packaging, labeling,

or holding operations for dietary supplements; environmental protection agency agricultural worker protection standards; and New Mexico department of agriculture (NMDA) pesticide registration, licensing and use requirements to ensure a safe product and environment;

- (6) the applicant's plan for the manufacture or distribution of cannabis derived products, including but not limited to edible products;
- (7) the security plan proposed, including location, security devices employed, and staffing;
- (8) the applicant's quality assurance plan, including but not limited to the applicant's plan to ensure purity, consistency of dose, as well as the applicant's plan for routine testing by a department approved laboratory;
- (9) the experience and expertise of the ~~non-profit~~ board members;
- (10) the financial resources available to the applicant for licensure and operations;
- (11) the facilities available to the applicant for production, distribution, storage, and other purposes, and the applicant's ownership of the property, buildings, or other facilities identified in the production and distribution plan, as applicable; and
- (12) other relevant factors.

G. [E.] Production and distribution of medical cannabis by a licensed ~~non-profit~~ producer; use of couriers: 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.

H. [F.] Verification of application information: The department may verify information contained in each application and accompanying documentation by:

- (1) contacting the applicant by telephone, mail, or electronic mail;
- (2) conducting an on-site visit;
- (3) requiring a face-to-face meeting and the production of additional identification materials if proof of identity is uncertain; and
- (4) requiring additional relevant information as the department deems necessary.

I. [G.] Cooperation with the department: Upon submitting an application, an applicant shall fully cooperate with the department and shall timely respond to requests for information or documentation. Failure to cooperate with a request of the department may result in the application being denied or otherwise declared incomplete.

J. [H.] Criminal history screening requirements: All persons associated with a licensed ~~non-profit~~ producer or ~~non-profit~~ producer-applicant, manufacturer or manufacturer-applicant, approved laboratory or laboratory applicant, and approved courier or courier-applicant, shall consent to and undergo a nationwide and department of public safety (DPS) statewide criminal history screening background check. This includes qualified patients, board members, persons having direct or indirect authority over management or policies, employees, contractors, and agents. Background check documentation shall be submitted annually for approval to the department with the applicant's renewal materials and prior to an individual assuming any duties or responsibilities for a ~~non-profit~~ producer, manufacturer, laboratory, or courier. Background check documentation shall be received by the medical cannabis program, and the individual shall be approved by the program, before the individual begins to provide any work or services to the producer, manufacturer, laboratory, or courier.

(1) **Criminal history screening fees:** All applicable fees associated with the nationwide and DPS statewide criminal history screening background checks shall be paid by the ~~non-profit~~ producer, manufacturer, laboratory, courier, or applicant.

(2) **Disqualifying convictions:** Individuals convicted of a felony violation of Section 30-31-20 (trafficking of a controlled substance); 30-31-21 (distributing a controlled substance to a minor); 30-31-22 NMSA 1978 (distributing a controlled substance); or a violation of any equivalent federal statute or equivalent statute from any other jurisdiction, shall be prohibited from participating or being associated with either a ~~non-profit~~

producer licensed under this rule, an approved laboratory, an approved manufacturer, or an approved courier. If an individual has been convicted of a felony violation of the NM Controlled Substances Act other than Sections 30-31-20 through 30-31-22 NMSA 1978, or has been convicted of any equivalent federal statute or equivalent statute from any other jurisdiction, and the final completion of the entirety of the associated sentence of such conviction has been less than five years from the date of the individual's anticipated association with the production facility, then the individual shall be prohibited from serving on the board of a licensed ~~non-profit~~ producer, or working for the licensed producer, or approved entity. An individual who is disqualified shall be notified of his or her disqualification. If an individual has been convicted of more than one felony violation of the above-cited sections of the NM Controlled Substances Act or an equivalent federal statute or equivalent statute from any other jurisdiction, the individual shall be notified that he or she is permanently prohibited from participating or being associated with a licensed ~~non-profit~~ producer, approved manufacturer, approved laboratory, or approved courier. Any violation of this subsection shall result in the immediate revocation of any privilege granted under this rule and the act.

K. [I.] Board membership requirements for private entities: The board of directors for a private ~~non-profit~~ applicant or licensee shall include at a minimum five voting members, including one medical provider limited to a physician (MD or DO), a registered nurse, nurse practitioner, licensed practical nurse, or physician assistant, and three patients currently qualified under the Lynn and Erin Compassionate Use Act.

(1) for purposes of board membership, a single individual may not qualify as both the patient and as the medical provider;

(2) members of the board of directors for a ~~non-profit~~ producer shall be residents of New Mexico; and

(3) no member of a ~~non-profit~~ producer's board of directors may at any given time serve on more than one single board of directors for licensed ~~non-profit~~ producers, or be employed by another ~~non-profit~~ producer.

L. [J.] Limitation on number of production facilities: A licensed ~~non-profit~~ producer shall conduct its production operations at a single, physical location approved by the department. An additional production facility or facilities may be allowed at the department's discretion if the ~~non-profit~~ producer is approved to grow more than 150 plants.

M. [K.] Limitation on sales within 90 consecutive calendar days: A licensed ~~non-profit~~ producer shall not sell or distribute usable cannabis to a qualified patient or primary caregiver in a total quantity that exceeds ~~230 units~~ **16 ounces**, as described in department rules concerning patient registry identification cards, within any 90-day period, unless the qualified patient or primary caregiver presents proof of a valid medical exception granted by the department.

N. [L.] ~~Maximum concentration of THC in concentrates:~~ A licensed ~~non-profit~~ producer shall not sell or otherwise distribute a concentrated cannabis derived product to a qualified patient or primary caregiver that contains greater than seventy percent (70%) THC by weight, unless the qualified patient or primary caregiver presents proof of a valid medical exception granted by the department. **Destruction of usable cannabis:** A licensed ~~non-profit~~ producer shall document the destruction of any usable cannabis using a video recording, and shall retain the video recording of the destruction for no less than one-hundred-and-twenty (120) days. A licensed ~~non-profit~~ producer shall make the video recording of the destruction available for the department's inspection or copying upon the department's request.

O. [M.] Maximum water content in dried usable cannabis: A licensed ~~non-profit~~ producer shall not sell usable cannabis, other than a cannabis derived product, that contains fifteen percent (15%) or greater water content by weight. A licensed ~~non-profit~~ producer may be subject to testing to ensure compliance, consistent with the provisions of this rule.

P. [N.] Non-profit producer policies and procedures: The ~~non-profit~~ producer shall develop, implement, and maintain on the premises policies and procedures relating to the medical cannabis program, which shall at a minimum include the following:

(1) distribution criteria for qualified patients or primary caregivers appropriate for cannabis services, to include clear, legible photocopies of the registry identification card and New Mexico photo identification card of every qualified patient or primary caregiver served by the private entity;

(2) testing criteria and procedures, which shall be consistent with the testing requirements of this rule;

(3) alcohol and drug-free work place policies and procedures;

(4) an attestation that no firearms will be permitted on any premises used for production or distribution by the ~~non-profit~~ entity;

(5) employee policies and procedures to address the following requirements:

- (a) job descriptions or employment contracts developed for every employee that identify duties, authority, responsibilities, qualifications, and supervision; and
- (b) training materials concerning adherence to state and federal confidentiality laws.
- (6) personnel records for each employee that include an application for employment and a record of any disciplinary action taken;
- (7) on-site training curricula, or contracts with outside resources capable of meeting employee training needs, to include, at a minimum, the following topics:
 - (a) professional conduct, ethics, and patient confidentiality; and
 - (b) informational developments in the field of medical use of cannabis.
- (8) employee safety and security training materials provided to each employee at the time of his or her initial appointment, to include:
 - (a) training in the proper use of security measures and controls that have been adopted; and
 - (b) specific procedural instructions regarding how to respond to an emergency, including robbery or a violent accident.
- (9) a general written security policy, to address at a minimum:
 - (a) safety and security procedures;
 - (b) personal safety; and
 - (c) crime prevention techniques.
- (10) training documentation prepared for each employee and statements signed by employees indicating the topics discussed (to include names and titles of presenters) and the date, time, and place the employee received said training;
- (11) a written policy regarding the right of the private entity to refuse service;
- (12) a confidentiality policy to ensure that identifying information of qualified patients is not disclosed or disseminated without authorization from the patient, except as otherwise required by the department; and
- (13) such other policies or procedures as the department may require.

Q. [Q.] Retention of training documentation: A ~~non-profit~~ producer shall maintain documentation of an employee's training for a period of at least six months after termination of an employee's employment. Employee training documentation shall be made available within 24 hours of a department representative's request; the 24 hour period shall exclude holidays and weekends.

R. [P.] Licensure periods:

(1) **Licensure period for ~~non-profit~~ producers:** The licensure period of a licensed ~~non-profit~~ producer shall be from August 1st (or the date of approval of the licensure application, if later) through July 31st of a given year.

(a) **Exception; transition to revised 2019 rules:** The licensure period for a licensed ~~non-profit~~ producer that would otherwise end on August 1, 2019 shall instead continue until September 30, 2019.

(2) **Licensure period for qualified patient producers:** A qualified patient's personal production license shall expire annually at the end of their enrollment in the NM medical cannabis program.

(3) **Return of a license or identification card:** Licenses and identification cards issued by the department are the property of the department and shall be returned to the department upon a producer's withdrawal from the program, upon termination of a card holder's employment with a licensed ~~non-profit~~ producer, or upon suspension or revocation.

S. [Q.] Amended license: A licensed producer shall submit to the department an application form for an amended license, and shall obtain approval from the department, at least 30 business days prior to implementing any:

- (1) change of location of a qualified patient who also holds a personal production license;
- (2) change of location of a ~~non-profit~~ producer's production or distribution facilities, change of directors, change of ownership of production or distribution facilities, private entity name, capacity or any physical modification or addition to the facility; and
- (3) substantial change to a private entity's production plan or distribution plan, including any change to the type(s) of products produced or distributed, the private entity's method(s) of distribution, and security plan.

T. [R.] Application for renewal of an annual production license:

(1) **Deadline for private entities.** Each licensed ~~non-profit~~ producer shall apply for renewal of its annual license no later than August 1st of each year by submitting a renewal application to the department. The department shall provide the renewal application requirements no later than June 1st of each year.

(2) **Deadline for personal production license holders:** A patient who holds personal production licensure shall apply for renewal of their annual license no later than 30 days prior to the expiration of the license by submitting a renewal application to the department.

(3) **General submission requirements for qualified patients:** Qualified patients applying for personal production licensure shall submit:

- (a) an application for issuance or renewal of a personal production license; and
 - (b) a non-refundable thirty dollar (\$30) application fee, except that the fee may be waived upon a showing that the income of the qualified patient is equal to or lesser than two hundred percent (200%) of the federal poverty guidelines established by the U.S. department of health and human services[~~;~~ and
 - (c) ~~a fifty dollar (\$50) payment, for replacement of a personal production license].~~
- A lost or stolen identification card shall be reported as soon as practicable to the medical cannabis program.

(4) **General submission requirements for private entities:** Private entities shall submit:

- (a) an application for renewal of license; and
- (b) applicable non-refundable licensure renewal fees.

U. [~~S.~~] Non-transferable registration of license:

(1) A license shall not be transferred by assignment or otherwise to other persons or locations. Unless the licensed producer applies for and receives an amended license, the license shall be void and returned to the department when any one of the following situations occurs:

- (a) ownership of the facility changes;
- (b) location change;
- (c) change in licensed producer;
- (d) the discontinuance of operation; or
- (e) the removal of all medical cannabis from the facility by lawful state authority.

(2) Transactions, which do not constitute a change of ownership, include the following:

- (a) when applicable, changes in the membership of a corporate board of directors or board of trustees; and
- (b) two or more corporations merge and the originally licensed corporation survives.

V. [~~T.~~] Automatic expiration of license:

(1) A license shall expire at 11:59 p.m. on the day indicated on the license as the expiration date, unless the license was renewed at an earlier date, suspended, or revoked.

(2) A private entity that intends to voluntarily close or is involuntarily closed shall notify the licensing authority no later than 30 calendar days prior to closure. All private ~~non-profit~~ entities shall notify all qualified patients or the primary caregivers prior to expiration of the license. Any unused medical cannabis shall be turned over to local law enforcement, destroyed by the producer, donated to patients, or provided to another ~~non-profit~~ producer to be donated to patients. A producer that destroys medical cannabis shall submit documentation of that destruction to the department.

W. [~~U.~~] Display of license: The licensed producer shall maintain the license safely at the production location and be able to produce the license immediately upon request by the department or law enforcement.

X. [~~V.~~] Fees applicable to applicants and licensees:

(1) **Non-profit Cannabis producer application fee:** A licensed cannabis producer applicant ~~non-profit~~ producer shall submit with its initial application an application fee of ten thousand dollars (\$10,000). If the application is denied, the department shall issue a refund of nine thousand dollars (\$9,000) to the applicant.

(2) **Non-profit Cannabis producer license fee:** A ~~non-profit~~ cannabis producer that is licensed shall submit to the medical cannabis program a non-refundable licensure fee before beginning operations, no earlier than July 1st of each renewal year and no later than August 1st of each renewal year, of **\$30,000 for the first 500 flowering cannabis plants; \$1,000 each for each additional increment of 100 flowering cannabis plants above 500 up to 2,000 flowering plants; and \$2,000 each for each additional increment of 100 flowering cannabis plants above 2,000;** ~~thirty thousand dollars (\$30,000); \$40,000 for the first [150] 500 cannabis plants to be possessed by the non-profit producer, and ten thousand dollars (\$10,000) for each additional quantity of 50 plants thereafter to be possessed, up to a maximum collective total of 450 cannabis plants]; \$5,000 for each additional increment of 50 cannabis plants above 500 and up to a collective total of 1,000 cannabis plants; and \$6,000 for each~~

~~additional increment of 50 cannabis plants above 1,000.~~

(3) **Exception; [F]transition to revised LNPP fees, plant limits:** A fee that is paid by a non-profit producer ~~[for the year 2015 and prior to the adoption of this rule shall be assessed, on a pro-rated basis,~~

~~towards the fees identified in this section for that licensure year~~ in the year 2019 shall be tendered to the department no earlier than September 23, 2019 and no later than October 4, 2019.

(4) **Qualified patient personal production fees:** A qualified patient shall submit with each initial application and renewal application for personal production licensure a fee of thirty dollars (\$30), except that the fee may be waived upon a showing that the income of the qualified patient is equal to or lesser than two hundred percent (200%) of the federal poverty guidelines established by the U.S. department of health and human services; and

(5) **Replacement license fee:** A fifty dollar (\$50) payment is required for replacement of ~~[a license]~~ an identification card for an employee of a licensed non-profit producer, and for replacement of a personal production license card.

(6) **Payment:** Fees shall be paid by check, money order, or any other form of payment approved by the medical cannabis program manager or designee, and shall be made payable to the medical cannabis program of the department.

Y. ~~[W.] Inventory and sales equipment:~~ The department may require a licensed ~~non-profit~~ producer to utilize specified equipment, software, and services for purposes of tracking inventory, sales, and other information, and for the purpose of reporting that information to the department of health.

[7.34.4.8 NMAC - Rp, 7.34.4.8 NMAC, 2/27/2015; A, 2/29/2016; A/E, 3/1/2019; A, xx/xx/2019]

7.34.4.18 QUALIFIED PERSONAL PRODUCTION APPLICATION AND LICENSURE REQUIREMENTS:

A. A qualified patient may apply for a personal production license for either the qualified patient or the qualified patient's primary caregiver to produce medical cannabis solely for the qualified patient's own use.

B. A qualified patient may obtain no more than one personal production license, which license may be issued for production to occur either indoors or outdoors in no more than one single location~~[, which shall be either the patient's primary residence or other property owned by the patient].~~

[7.34.4.18 NMAC - Rp, 7.34.4.9 NMAC, 2/27/2015]

7.34.4.19 ~~NON-PROFIT~~ PRODUCER APPLICATION AND LICENSURE REQUIREMENTS:

B. Production and distribution information and materials: An applicant for ~~non-profit~~ producer licensure shall submit to the department:

(1) an acknowledgement that production, at any time, shall not exceed the total of cannabis ~~[mature female [plants, seedlings, and male] plants that the non-profit entity has been approved to produce as well as an inventory of usable cannabis that reflects current patient needs;~~

[7.34.4.19 NMAC - Rp, 7.34.4.8 & 10 NMAC, 2/27/2015; A, 2/29/2016; A, xx/xx/2019]

7.34.4.23 MONITORING AND CORRECTIVE ACTIONS:

B. Financial records: A licensed ~~non-profit~~ producer shall maintain detailed confidential sales records in a manner and format approved by the department, and shall inform the department of the location where such records are kept, and promptly update that information if the records are removed.

(1) **Access:** The department and its agents shall have reasonable access to the sales and other financial records of a licensed ~~non-profit~~ producer, including data from point of sale systems, and shall be granted immediate access to inspect or copy those records upon request. A patient shall be granted reasonable access to a licensed ~~non-profit~~ producer's sales records for that patient upon request.

(2) **Audit:** A licensed ~~non-profit~~ producer shall submit the results of an annual audit to the department no later than 90 days after the end of each fiscal year of the licensed ~~non-profit~~. For the purposes of this

section, the fiscal year of a ~~non-profit~~ producer shall be the 12 month cycle identified by the producer in its filings with the New Mexico taxation and revenue department. The annual audit shall be conducted by an independent certified public accountant; the costs of any such audit shall be borne by the private entity. Results of the annual audit shall be forwarded to the medical cannabis program manager or designee. The department may also periodically require, within its discretion, the audit of a ~~non-profit~~ producer's financial records by the department.

(3) **Quarterly reports:** A ~~non-profit~~ producer shall submit reports on at least a quarterly basis, or as otherwise requested, and in the format specified by the department. The quarterly report shall include at a minimum:

- (a) Number of qualified patients and primary caregivers who purchased usable Cannabis, as calculated or tracked through the BioTrack database system;
- (b) Total number of retail transactions, as calculated or tracked through the BioTrack database system;
- (c) Average amount (in ounces or grams ~~units~~) purchased per retail transaction, as calculated or tracked through the BioTrack database system;
- (d) Number of units provided without charge, as calculated or tracked through the BioTrack database system;
- (e) Number of cannabis plants in production, including mature plants and seedlings, as calculated or tracked through the BioTrack database system;
- (f) Number of cannabis plants harvested, as calculated or tracked through the BioTrack database system;
- (g) Total yield of usable cannabis harvested from cannabis plants (in grams), as calculated or tracked through the BioTrack database system;
- (h) Average yield per plant (in grams);
- (i) Amount of cannabis (in grams) sold by wholesale, as calculated or tracked through the BioTrack database system;
- (j) Amount of cannabis (in grams) purchased by wholesale, as calculated or tracked through the BioTrack database system;
- (k) Number of live cannabis plants (including clones) and cannabis seeds sold, as calculated or tracked through the BioTrack database system;
- (l) Amount of dried cannabis leaves and flowers in stock, as calculated or tracked through the BioTrack database system;
- (m) Average price per gram of dried cannabis leaves and flowers, as calculated or tracked through the BioTrack database system;
- (n) Total amount of dried cannabis leaves and flowers sold (in units), as calculated or tracked through the BioTrack database system;
- (o) Total sales of dried cannabis leaves and flowers (in dollars and units), as calculated or tracked through the BioTrack database system;
- (p) Amount of cannabis derived products in stock (in units), as calculated or tracked through the BioTrack database system;
- (n) Total amount of cannabis derived products sold (in ounces or grams) ~~units~~, as calculated or tracked through the BioTrack database system;
- (o) Total sales of cannabis derived products (in dollars and ounces or grams) ~~units~~, as calculated or tracked through the BioTrack database system;
- (p) Amount of gross receipts tax paid to the New Mexico department of taxation and revenue;
- (q) All quality testing reports, to be included as attachments;
- (r) A detailed description of any thefts, robberies, break-ins or security breaches that occurred, including a description of any property that was stolen or destroyed, and the quantity of any usable cannabis that was stolen; and
- ~~(s) Such additional information as the department may request.~~

(4) **BioTrack Report Equivalency;** for purposes of quarterly reports, the Department shall accept as equivalent and sufficient reports derived from the BioTrack database regarding the subject categories. The Department shall accept the BioTrack reports in their native form as derived from the BioTrack software system.

(5) **Measurement of Ounces or Grams;** for cannabis-derived products and concentrated cannabis-derived products, the weight of usable cannabis shall be calculated by the weight of cannabis plant material and/or cannabis oils present in the product. The weight of non-cannabis materials, including foods, in the product shall not be considered or calculated toward the total weight of usable cannabis.

(s) Such additional information as the department may request.

[7.34.4.23 NMAC - Rp, 7.34.4.15 NMAC, 2/27/2015; A, xx/xx/2019]

7.34.4.24 DISCIPLINARY ACTIONS AND APPEAL PROCESS:

A. Grounds for disciplinary action: Whenever the Department determines that a person violated or is violating the Lynn and Erin Compassionate Use Act or any provision of any rule, order, permit, or authorization issued pursuant to that act, the Department of Health may seek compliance and civil penalties by:

- (1) Issuing a notice of violation;
- (2) Commencing a departmental hearing and disciplinary proceeding if the person fails to resolve the violation; or
- (3) commencing a civil action in district court for appropriate relief, including injunctive relief.

~~**B.** Disciplinary action may be taken against a producer applicant, a licensed producer, a manufacturer applicant or approved manufacturer, a laboratory applicant or approved laboratory, or an approved courier or courier applicant. Disciplinary action may include revocation, suspension, or denial of an application, license, or department approval, monetary penalties, and other action. Disciplinary action may be imposed for:~~

- ~~(1) failure to comply with or satisfy any provision of this rule;~~
- ~~(2) falsification or misrepresentation of any material or information submitted to the department;~~
- ~~(3) failing to allow or impeding a monitoring visit by authorized representatives of the department;~~
- ~~(4) failure to adhere to any acknowledgement, verification, or other representation made to the department;~~
- ~~(5) failure to submit or disclose information required by this rule or otherwise requested by the department;~~
- ~~(6) failure to correct any violation of this rule cited as a result of a review or audit of~~

~~financial records or other materials;~~

- ~~_____ (7) failure to comply with the department's requested access to premises or materials;~~
- ~~_____ (8) failure to pay a required monetary penalty;~~
- ~~_____ (9) diversion of cannabis or a cannabis-derived product, as determined by the department;~~
- ~~_____ (10) threatening or harming a patient, a medical practitioner, or an employee of the department; and~~
- ~~_____ (11) any other basis identified in this rule.]~~
- (1) A major violation implicating public safety consists of the following, including:
 - (a) failure to comply with or satisfy any provision of this rule that implicates public safety;
 - (b) diversion of cannabis or a cannabis-derived product, as determined by the department;
 - (c) threatening or harming a patient, a medical practitioner, or an employee of the department;
 - (d) intentionally destroying, damaging, altering, removing or concealing evidence of a violation under this rule, attempting to do so, or asking or encouraging another person to do so;
 - (e) deliberately purchasing usable cannabis, cannabis-derived products or cannabis plants from out of state or outside the legal medical cannabis system; or
 - (f) other conduct that shows willful or reckless disregard for health or safety;
- (2) A major violation not implicating public safety consists of the following, including:
 - (a) failure to pay a required monetary penalty;
 - (b) failure to comply with the department's requested access to premises or materials;
 - (c) failure to allow or impedance of a visit by authorized representatives or designees of the department;
 - (d) falsification or misrepresentation of any material or information submitted to the department;
 - (e) failure to adhere to any acknowledgement, verification, or other representation made to the department;
 - (f) failure to submit or disclose information required by this rule or otherwise requested by the department;
 - (g) failure to correct any violation of this rule cited as a result of a review or audit of financial records or other materials, or cited as a result of a monitoring visit or site inspection;
 - (h) a pattern of non-major license violations;
 - (i) noncompliance with tax obligations as determined by a taxation regulatory authority;
 - (j) exceeding the plant limit of the license; and
- (3) Any other violation consists of, including:
 - (a) failure to comply with or satisfy any provision of this rule that does not implicate public safety;
 - (b) failure to take a video recording of the destruction of usable cannabis, in accordance with this rule; and
 - (c) selling or transferring to a qualified patient or primary caregiver a quantity of usable cannabis greater than the maximum amount permitted by department rule.

C. Notice of Violation: The Department shall issue a notice of violation prior to levying any fine or taking any disciplinary action. A notice of violation issued pursuant to this section shall state with specificity the nature of the violation, shall require compliance immediately or within a specified time period, shall provide notice of the availability of an informal review and the date of a hearing before the division and shall provide notice of potential sanctions, including assessing a penalty; suspending, canceling, or terminating a license or authorization.

D. Failure to Cure a Notice of Violation: If the notice of violation is not resolved informally within thirty days after service of the notice by the Department upon a licensed entity, the Department shall hold a hearing and determine whether the violation should be upheld and whether any sanctions, including civil penalties, shall be assessed. In assessing a penalty authorized by this section, the Department shall take into account the seriousness of the violation, any good faith efforts to comply with the applicable requirements, any history of noncompliance by the person, and other relevant factors. When a decision is rendered by the Department after a hearing, any party of record adversely affected shall have the right to appeal the adverse decision by Rule 1-074 NMRA and/or Rule 1-075 NMRA.

E. Fines Not to Exceed: Any civil penalty assessed by a court or by the Department pursuant to this

section shall not exceed \$1,000 per day of noncompliance for each violation, unless the violation presents a risk either to the health or safety of the public or of causing significant public harm, or unless the noncompliance continues beyond a time specified in the notice of violation or order issued by the Department. In the case of a violation presenting risk to health or safety, a violation causing significant public harm, or a violation continuing beyond a time specified in the notice of violation or order issued by the Department, a civil penalty may not exceed \$3,000 per day of noncompliance for each violation. In no case may any penalty assessed by the Department exceed \$25,000.

F. Suspensions: Any suspension of activity assessed by a court or by the Department pursuant to this section shall not cause a licensee to forego more than \$30,000 of gross revenue, unless the violation presents a risk either to the health or safety of the public or of causing significant public harm and the noncompliance continues beyond a time specified in the notice of violation or order issued by the Department.

~~**C. Fines:** Disciplinary actions against a licensed non-profit licensed cannabis producer, approved manufacturer, approved laboratory, or approved courier may include the imposition of monetary penalties, which may be assessed by the department in the amount of:~~

~~(1) [one hundred dollars (\$100) for the first assessed monetary penalty in a calendar year] up to \$50,000 for each major violation implicating public safety;~~

~~(2) [five hundred dollars (\$500) for the second assessed monetary penalty in a calendar year] up to \$20,000 for each major violation not implicating public safety;~~

~~(3) [one thousand dollars (\$1,000) for every monetary penalty thereafter assessed in a calendar year] up to \$5,000 for each other violation.~~

[7.34.4.24 NMAC - Rp, 7.34.4.16 NMAC, 2/27/2015; A, xx/xx/2019]

7.34.4.25 EXEMPTION FROM STATE CRIMINAL AND CIVIL PENALTIES [~~FOR THE MEDICAL USE OF CANNABIS~~]:

C. In accordance with the Public School Code, Chapter 22 NMSA 1978, and the Lynn and Erin Compassionate Use Act at NMSA 1978, § 26-2B-4(G), the department hereby deems New Mexico public schools, school districts, local school boards, locally-chartered charter schools, state-chartered charter schools, and governing bodies of state-chartered charter schools to be licensees, and designated school personnel (including designated employees and volunteers of the foregoing licensees) to be licensee representatives, authorized within the licensees' licensure to possess and store cannabis and cannabis derived products on behalf of qualified students, and to administer cannabis and cannabis derived products to qualified students, in school settings. The department deems the licensees and licensee representatives to be entitled to immunity from arrest, prosecution or penalty, in any manner, for activities conducted within the licensees' licensure and in accordance with the Public School Code. [7.34.4.25 NMAC - Rp, 7.34.4.17 NMAC, 2/27/2015; A, xx/xx/2019]

I, Bryan Sullivan, representative of Keyway Inc DBA Shift contend that I support the Comments on Proposed Rules titled "Cannabis Producers Comments on Proposed Rules" as submitted on July 11, 2019, with the exception of changes in manufacturing licensing fees.

Name: Bryan Sullivan

Date 7/11/19

Signature: 

I, DARREN WHITE, representative of Purlife and MJ Express O, contend that I support the Comments on Proposed Rules titled "Cannabis Producers Comments On Proposed Rules", except for **7.34.4.7(Y) NMAC and 7.34.4.9(A)(2): Because of the Clone-Based Growing System, a Limitation of 1,750 Plants Greater than 8-Inches Is, in Operation, a Hard Limitation of 1,750 plants and 7.34.4.8(A)(1), 7.34.4.8(A)(1), 7.34.3.9: There Is No Logical Relationship Between Personal Production Limitations, Adequate Supply, and Producer Plant Limitation**, as submitted on July 11, 2019.

Name: DARREN WHITE
Signature: Darren White

Date 7-11-19

I, TREVOR REED, representative of NATURALFX
contend that I support the Comments on Proposed Rules titled "Cannabis
Producers Comments On Proposed Rules" as submitted on July 11, 2019.

Name: TREVOR REED

Date 7-9-19

Signature: 

* MY VARIANT ON THE "CANNABIS PRODUCERS COMMENTS
ON PROPOSED RULES" IS AS FOLLOWS:

NEW MEXICO HAS A PROBLEM WITH BLACK MARKET AND
GREY MARKET CANNABIS, FOR THIS REASON IF THE
SUPPLY WAS AT ROBUST LEVELS IT COULD HELP MITIGATE
THE ISSUE.

MY PERSONAL THOUGHTS ARE THAT IT IS NOT AS
SIMPLE AS A PLANT COUNT. MOST GROWERS WITH
THE NEW PLANT COUNT ARE LAZY AND ARE
GOING TO PLACE 6-9 PLANTS BENEATH A
1000 W LIGHT INDOORS. THE NET RESULT

I, Brett A. Baker, representative of Red Barn Growers
contend that I support the Comments on Proposed Rules titled "Cannabis
Producers Comments On Proposed Rules" as submitted on July 11, 2019.

Name: Bret A. Baker

Date 7/11/2019

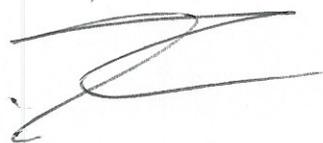
Signature: BA A. Baker

IN PRODUCED GRAMS OF USABLE CANNABIS
WILL BE SLIGHTLY MORE. I FEEL THAT A
CANOPY LIMIT FOR INDOOR, OUTDOOR, GREENHOUSE
WOULD BE MORE APPROPRIATE. THERE ALSO
IS A PLACE TO TIER THE AMOUNTS A LNDP
COULD GROW, SOME ARE CONTENT MANAGING
A SMALLER GARDEN.

I ~~WANT~~ LIKE THE PROVISION FOR INCREASING
THE PLANT COUNT IN THE CASE OF AN LNDP
PROVING AN INTERNAL NEED FOR CANNABIS.

LASTLY, THE FEES ARE NOT BOTHERING SOME
TO ME. I FEEL THAT IF A COMPANY
CAN'T MAKE MONEY SELLING LEGAL CANNABIS
THEY SHOULD, WELL I AM NOT SURE WHAT,
BUT THEY ARE NOT GOOD WITH BUSINESS!

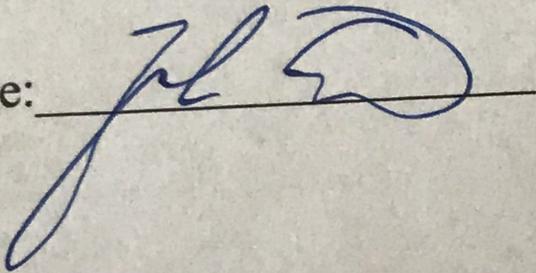
Respectfully



I, Zeke Shortes, representative of Sacred Garden
contend that I support the Comments on Proposed Rules titled "Cannabis
Producers Comments On Proposed Rules" as submitted on July 11, 2019.

Name: Zeke Shortes

Date 7/10/19

Signature: 

I, Jason Lareathouse, representative of Pecos Valley Production contend that I support the Comments on Proposed Rules titled "Cannabis Producers Comments On Proposed Rules" as submitted on July 11, 2019.

Name: Jason Lareathouse

Date 7/9/19

Signature: 

I, Barbara Crawford, representative of Southwest Wellness
contend that I support the Comments on Proposed Rules titled "Cannabis
Producers Comments On Proposed Rules" as submitted on July 11, 2019.

Name: Barbara Crawford

Date 7/10/19

Signature: 

I, David Muscarella, representative of Urban Wellness, with the exception of the comments related to Section 7.34.4.8 (A)(2), support the Comments on Proposed Rules titled “Cannabis Producers Comments On Proposed Rules” as submitted on July 11, 2019.

Name: David Muscarella

Date July 10, 2019

Signature:

A handwritten signature in black ink, appearing to read "David Muscarella", written over a horizontal line.

I, Brently Levesque, representative of Sandica Botanicals
contend that I support the Comments on Proposed Rules titled "Cannabis
Producers Comments On Proposed Rules" as submitted on July 11, 2019.

Name: Brently Levesque

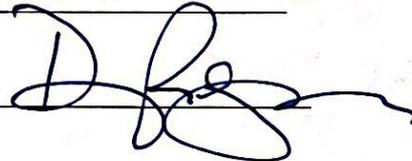
Date 7-10-2019

Signature: 

I, DUKE RODRIGUEZ, representative of ULTRA HEALTH
contend that I support the Comments on Proposed Rules titled "Cannabis
Producers Comments On Proposed Rules" as submitted on July 11, 2019.

Name: DUKE RODRIGUEZ

Date July 10th, 2019

Signature: 

I, Fredrick Lucas, representative of Kure Inc.
contend that I support the Comments on Proposed Rules titled “Cannabis
Producers Comments On Proposed Rules” as submitted on July 11, 2019.

Name: Fredrick Lucas, President

Date 07.10.19

Signature: _____

I, Andrew Gordon, representative of G and G Genetics contend that I support the Comments on Proposed Rules titled "Cannabis Producers Comments on Proposed Rules" as submitted on July 11, 2019.

Name: Andrew Gordon

Date JULY 9, 2019

Signature: 

STATE OF NEW MEXICO
FIRST JUDICIAL DISTRICT COURT
SANTA FE COUNTY

NICOLE SENA, individually and as
Next friend to A.N., a minor, and
NEW MEXICO TOP ORGANICS – ULTRA HEALTH, INC.,
A New Mexico non-profit corporation,

Plaintiffs,

v.

No. D-101-CV-2016-01971

NEW MEXICO DEPARTMENT OF HEALTH, and
LYNN GALLAGHER, in her official capacity as
Secretary-Designate,

Defendants.

ORDER

This matter comes before the Court after a trial on the merits conducted August 14, 2017 through August 17, 2017 with Judge David K. Thomson, and the Court having conducted a trial on the merits, having read closing briefs , and being otherwise duly advised on the premises,

FINDS:

DEFINITIONS:

A. “Act” means the Lynn and Erin Compassionate Use Act, NMSA 1978, Sections 26-2B-1 through 26-2B-7.

NMAC 7.34.4

O. “Department” means the New Mexico Department of Health or its agent.

NMAC 7.34.4. (also referred in the Order as “DOH”)

JURISDICTION AND PARTIES:

Personal jurisdiction of the Court over the parties is not disputed and is hereby determined to be present. The Defendants have maintained that the Court lacks subject matter jurisdiction 1) insofar as the requested relief is contrary to and prohibited by the separation of

powers identified in the New Mexico Constitution; and 2) insofar as the Plaintiffs have standing to pursue the asserted claims and no legitimate case or controversy exists. As stated,

The limitations we have placed on the use of the declaratory judgment action respect the role of each branch of government in the constitutional scheme and the administrative processes put in place by the Legislature. Article III, Section 1 of the New Mexico Constitution divides state government into “three distinct departments, the legislative, executive and judicial.” Although we have recognized “that the constitutional doctrine of separation of powers permits some overlap of governmental functions,” *State ex rel. Taylor v. Johnson*, 1998–NMSC–015, ¶ 23, 125 N.M. 343, 961 P.2d 768, it remains true that “[w]ithin our constitutional system, each branch of government maintains its independent and distinct function.” *Id.* ¶ 21 (citing *State v. Fifth Judicial Dist. Court*, 36 N.M. 151, 153, 9 P.2d 691, 692 (1932) for the proposition that “[t]he Legislature makes, the executive executes, and the judiciary construes the laws.”). Within this constitutional scheme, we have recognized the Legislature's power to delegate both adjudicative and rule-making power to administrative agencies. *See Bd. of Educ. of Carlsbad Mun. Sch. v. Harrell*, 118 N.M. 470, 483–84, 882 P.2d 511, 524–25 (1994) (citing *Wylie Corp. v. Mowrer*, 104 N.M. 751, 753, 726 P.2d 1381, 1383 (1986), for the proposition that the Legislature may delegate adjudicatory power to agencies); *Duke City Lumber Co. v. N.M. Envtl. Improvement Bd.*, 101 N.M. 291, 292, 681 P.2d 717, 718 (1984) (observing that the Legislature “grants agencies the discretion of promulgating rules and regulations which have the force of law”). Courts should not intervene to halt administrative hearings before rules or regulations are adopted. To do so would thwart the public's opportunity to participate in rule-making. Because of the necessity to respect the separate branches of government, courts should not intervene to halt administrative hearings before rules or regulations are adopted. To do so could deprive the public of the opportunity to propose rules or regulations and otherwise participate in the rule-making process. In addition, the administrative agency should be given the opportunity to correct any errors that have been brought to its attention during the course of such proceedings.

New Energy Econ., Inc. v. Shoobridge, 2010-NMSC-049, ¶ 14, 149 N.M. 42, 47, 243 P.3d 746, 751

As is more thoroughly discussed in the conclusions of law, this Court has original jurisdiction over the claims at issue due to the Agency's failure to comply with the mandates of the Lynn and Erin Compassionate Use Act by creating a 450 plant limit on producers. This Court is construing the statute at issue, with respect to the Agency's conclusions that a 450 plant count is appropriate.

As stated in *El Castillo*, this Court has original jurisdiction over the dispute,

The Legislature conferred power in the district court to review, as a court of first appeal, a final decision of the Board. *See* NMSA 1978, § 7-38-28(A) (2015); NMSA 1978, § 39-3-1.1 (1999). When acting in its appellate role, the district court may reverse an agency decision if it determines that “(1) the agency acted fraudulently, arbitrarily, or capriciously; (2) the final decision was not supported by substantial evidence; or (3) the agency did not act in accordance with law.” Section 39-3-1.1(D). The district court, in its appellate capacity, “is limited in the same manner as any other appellate body ... and must defer to the agency's factual determinations if supported by substantial evidence.” *N.M. Bd. of Psychologist Exam'rs v. Land*, 2003-NMCA-034, ¶ 5, 133 N.M. 362, 62 P.3d 1244.

In addition to its appellate jurisdiction, the district court has “original jurisdiction in all matters and causes not excepted in this constitution.” N.M. Const. art. VI, § 13. The district court is a court of general jurisdiction and has the authority to consider all matters not exclusive to other courts, including constitutional claims in the first instance. *Maso v. N.M. Tax'n & Revenue Dep't*, 2004-NMCA-025, ¶ 14, 135 N.M. 152, 85 P.3d 276 (“[T]he district court has the authority to consider constitutional claims in the first instance.”).

A “district court can simultaneously exercise its appellate and original jurisdiction.” *Id.* ¶ 17. On appeal to a district court of claims first considered by an agency, where the appeal also asserts constitutional and other claims in the district court that were beyond the scope of the agency's adjudicative authority, “the district court should consider each claim according to its appropriate standard of review and maintain the distinction between the court's appellate and original jurisdiction in rendering its decision.” *Id.*

El Castillo Ret. Residences v. Martinez, 2017-NMSC-026, ¶¶ 21-24, 401 P.3d 751, 757–58

In the *City of Santa Fe* case the Supreme Court stated:

The Declaratory Judgment Act is a special proceeding that grants the district courts the “power to declare rights, status and other legal relations whether or not further relief is or could be claimed.” NMSA 1978, § 44-6-2 (1975). “The Declaratory Judgment Act [is] intended to be liberally construed and administered as a remedial measure.” *San Juan Water Comm'n v. Taxpayers & Water Users of San Juan County*, 116 N.M. 106, 109, 860 P.2d 748, 751 (1993). “The Act does not enlarge the jurisdiction of the courts over subject matter and parties, but provides an alternative means of presenting controversies to courts having jurisdiction thereof...” *Allstate Ins. Co. v. Firemen's Ins. Co.*, 76 N.M. 430, 432, 415 P.2d 553, 554 (1966).

9 {14} Of particular relevance to this case, the Act grants jurisdiction to the district court to entertain an action for a declaratory judgment to review municipal

ordinances. Such jurisdiction is provided in **305 *791 NMSA 1978, Section 44-6-4 (1975), which provides that “[a]ny person ... whose rights, status or other legal relations are affected by a ... municipal ordinance ... may have determined any question of construction or validity arising under the ... ordinance....” Thus, the Declaratory Judgment Act is specifically designed to bring an action challenging the constitutionality or validity of local laws or ordinances. *See, e.g., Balizer v. Shaver*, 82 N.M. 347, 349, 481 P.2d 709, 711 (Ct.App. 1971) (holding that declaratory proceedings are a proper avenue for testing the constitutionality of municipal ordinances); *see also S. Nat’l Bank of Houston v. City of Austin*, 582 S.W.2d 229, 237 (Tex.Civ.App.1979) (finding declaratory judgment proper where property owners challenged city ordinance); *Ind. Waste Systems, Inc. v. Bd. of Comm’rs of Howard County*, 180 Ind.App. 385, 389 N.E.2d 52, 56 (1979) (holding that a declaratory judgment action was proper to challenge the validity of a county ordinance); *Kmiec v. Town of Spider Lake*, 60 Wis.2d 640, 211 N.W.2d 471, 473 (1973) (holding that a declaratory judgment action was a proper avenue for challenging the validity of an ordinance); *Sorenson v. City of Bellingham*, 80 Wash.2d 547, 496 P.2d 512, 517 (1972) (“The use of declaratory judgment to determine rights in this matter without a course of remedy is entirely appropriate.”); *Walker v. Los Angeles County*, 55 Cal.2d 626, 12 Cal.Rptr. 671, 361 P.2d 247, 253 (1961) (“The interpretation of ordinances and statutes are proper matters for declaratory relief.”). *See generally* 6 Eugene McQuillin, *The Law of Municipal Corporations*, § 20.23, at 72 (3d ed.); Bernard Schwartz, *Administrative Law* § 9.7, at 537 (2d ed. 1984) (“[T]he declaratory judgment has become the general-utility remedy by which the legality of an administrative act may be determined when there are no statutory review provisions, regardless of the nature of the challenged act.”).

Smith v. City of Santa Fe, 2007-NMSC-055, ¶¶ 13-14, 142 N.M. 786, 790–91, 171 P.3d 300, 304–05

Under *El Castillo* and *City of Santa Fe*, the Court has jurisdiction to proceed.

LAWS APPLICABLE TO THE DISPUTE:

The Department’s duties are defined as:

A. No later than October 1, 2007, and after consultation with the advisory board, the department shall promulgate rules in accordance with the State Rules Act to implement the purpose of the Lynn and Erin Compassionate Use Act. The rules shall:

(1) govern the manner in which the department will consider applications for registry identification cards and for the renewal of identification cards for qualified patients and primary caregivers;

- (2) define the amount of cannabis that is necessary to constitute an adequate supply, including amounts for topical treatments;
- (3) identify criteria and set forth procedures for including additional medical conditions, medical treatments or diseases to the list of debilitating medical conditions that qualify for the medical use of cannabis. Procedures shall include a petition process and shall allow for public comment and public hearings before the advisory board;
- (4) set forth additional medical conditions, medical treatments or diseases to the list of debilitating medical conditions that qualify for the medical use of cannabis as recommended by the advisory board;
- (5) identify requirements for the licensure of producers and cannabis production facilities and set forth procedures to obtain licenses;
- (6) develop a distribution system for medical cannabis that provides for:
 - (a) cannabis production facilities within New Mexico housed on secured grounds and operated by licensed producers; and
 - (b) distribution of medical 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;
- (7) determine additional duties and responsibilities of the advisory board; and
- (8) be revised and updated as necessary.

NMSA 1978 § 26-2B-7

Adequate supply is defined as,

A. "Adequate supply" means 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;

NMSA 1978 § 26-2B-3

It is defined in regulation as,

B. "Adequate supply" means an amount of cannabis, derived solely from an intrastate source and in a form approved by the department, that is possessed by a qualified patient or collectively possessed by a qualified patient and the qualified patient's primary caregiver, that is determined by the department to be no more than reasonably necessary to ensure the uninterrupted availability of cannabis for a period of three months or 90 consecutive calendar days.

NMAC 7.34.4

The disputed provision is outlined in ¶ 2 below:

7.34.4.8 PRODUCER LICENSING; GENERAL PROVISIONS:

A. The department may license two classes of producers:

(1) A qualified patient who holds a valid personal production license. A qualified patient 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. A personal production license holder may additionally obtain usable cannabis, seeds, or plants from licensed non-profit producers. The primary caregiver of a qualified patient who holds a personal production license may assist the qualified patient to produce medical cannabis at the designated licensed location that is identified on the personal production license; the primary caregiver may not independently produce medical cannabis.

(2) A non-profit producer that operates a facility and, at any one time, is limited to a combined total of no greater than 450 mature female plants, seedlings and male plants, and an inventory of usable cannabis and seeds that reflects current patient needs, and that shall sell cannabis with a consistent unit price, without volume discounts or promotional sales based on the quantity purchased. A non-profit producer shall not possess a quantity of either mature female plants or seedlings and male plants that exceeds the quantities authorized by their licensure and associated licensing fee. A licensed non-profit producer may sell and distribute usable cannabis to a person or entity authorized to possess and receive it. A licensed non-profit producer may obtain plants, seeds and usable cannabis from other licensed non-profit producers.

NMAC 7.34.4

A. “Act” means the Lynn and Erin Compassionate Use Act, NMSA 1978, Sections 26-2B-1 through 26-2B-7.

NMAC 7.34.4

O. “Department” means the Department of Health or its agent.

NMAC 7.34.4

GENERAL NATURE OF THE CLAIMS:

Plaintiffs bring a declaratory judgment seeking to eliminate/invalidate the Department of Health (“DOH”) regulation which mandates that licensed non-profit producers of medical cannabis products may possess no more than 450 plants at any given time. *See* Complaint

8/16/2016 at Count 1 ¶88. Plaintiff Sena is the parent of a minor child who is currently a patient enrolled in New Mexico's Medical Cannabis Program. Plaintiff Sena's child has a rare form of epilepsy, the symptoms of which are relieved by medical cannabis products, including CBD oil. The treatment for Plaintiff Sena's child requires a significant amount of cannabis material, and she has difficulty finding licensed non-profit producers who can provide sufficient medicine for her child's treatment.

Plaintiff New Mexico Top Organics-Ultra Health ("Ultra Health") is a licensed non-profit producer of medical cannabis products which seeks to meet the needs of all people in New Mexico who may have medical conditions which can be alleviated or treated with medical cannabis.

Plaintiffs claim that the Department of Health regulation which limits licensed non-profit producers to 450 plants creates barriers to the realization of the purpose of the Lynn and Erin Compassionate Use Act and creates barriers to patients being able to access the medication they need. Plaintiffs also claim that the regulatory limit of 450 plants is not justified by data or by legal considerations and that DOH lacks the capacity or ability to make data-driven decisions regarding plant-count limitations.

Plaintiffs further claim DOH chose the 450 figure arbitrarily—that it was simply a number which was between 100 and 1,000. In coming to the 450 figure, DOH has emphasized its consideration of federal criminal penalties. Those penalties have brackets of 0-99 plants, 99-999 plants, and 1,000-plus plants. Plaintiffs claim the 450 figure is not supported or connected to any relevant data points, such as data on patient consumption, patient need, producer capacity, etc.

Additionally, Plaintiffs claim the plant count limitation creates barriers to the fulfillment of the purpose of the Medical Cannabis Program because it prevents the creation of economies of scale, prevents producers from being responsive to patient needs, creates artificially high prices, and fails to drive down costs despite growing demand.

Finally, Plaintiffs claim that any plant count is outside the scope of authority of DOH. NMSA § 26-2B-4 fails. Defendants deny Plaintiffs' allegations. Defendants argue they have broad statutory authority to create the plant limit under their regulatory authority and that the plant limit meets their obligation to ensure adequate supply.

QUESTION PRESENTED

The question presented by the statute, therefore, is "[d]oes the Act allow DOH to regulate the quantity of cannabis a licensed non-profit producer may produce, possess, distribute, or dispense?", and "may DOH in executing their regulatory authority impose a count limit that impedes the purpose of the Act which is to provide an adequate supply of cannabis?"

SUMMARY OF DECISION

DOH has a duty/obligation to ensure that patients can obtain an "adequate supply" of medical cannabis products, and therefore DOH has a duty to adequately study and evaluate whether patients can obtain such an adequate supply. Plaintiffs claim is substantiated that DOH is not fulfilling its obligations because its data collection is unreliable and because its evaluation of supply is baseless and unreliable. To do this, they must make sure its decision is neither arbitrary nor capricious. Further, they may not rely on their regulatory authority as a pretext for justifying limiting "adequate supply". That is DOH may not use a statutory grant of the power to regulate to impede the fundamental duty under the act which is to ensure an adequate supply.

DOH has been on notice for several years of shortages of medical cannabis supply and that patients cannot obtain necessary amounts of medication. Plaintiffs claim DOH's lack of response to this notice indicates it does not have a valid reason or explanation for its 450 plant count limitation. The Court's decision is further summarized as follows:

1. Plaintiffs' request for relief in the form of Declaratory Judgment invalidating and eliminating the 450 plant count limitation as contrary to the Lynn and Erin Compassionate Use Act is **GRANTED**. The Order invalidating the plant limit is stayed for 120 days to allow DOH to conduct appropriate fact finding procedures to arrive at a plant count limitation that complies with the legislative mandate.

2. That the Lynn and Erin Compassionate Use Act at NMSA 1978, §26-2B-7 confers to the New Mexico Department of Health broad discretion to develop the distribution system for medical cannabis within the New Mexico Medical Cannabis Program ("Program") and to "identify requirements for the licensure of producers and cannabis production facilities and set forth procedures to obtain licenses", but is not a grant to limit the production of medicinal cannabis that has no articulated fact based correlation between the 450 plant limit and what meets the adequate supply needs of patients.

3. The stated purpose of the Lynn and Erin Compassionate Use Act at NMSA 1978, §26-2B-2 is to "to allow the beneficial use of medical cannabis in a regulated system for alleviating symptoms caused by debilitating medical conditions and their medical treatments." The Lynn and Erin Compassionate Use Act does express legislative intent regarding the number of producers to be licensed, and the number of plants to be possessed by individual producers, and that this determination is within the New Mexico Department of Health's statutory authority.

4. Although the Department of Health has endeavored to ensure the general availability of cannabis within the Program, DOH has failed to ensure that there is an adequate supply within the Program as to cannabis in general or as to any given cannabis products.

5. That the plant count limit imposed upon by DOH has prohibited the Plaintiff Nicole Sena from obtaining a given type of cannabis product and limited her ability to provide a medical benefit to her child. Anyone concerned about the benefits of CBD oil to her daughters condition, or her belief that CBD is medically beneficial may reach only one conclusion after hearing her testimony.

6. DOH has not revisited the 450 plant count limitation since 2014, even as the patient enrollment in the Medical Cannabis Program continues to grow. DOH has defended the figure and has claimed that 450 plants-per-producer is currently meeting patient needs. However, data collected and compiled by DOH is irregular, arbitrary, and inaccurate. DOH has simply relied on the theory that based on a 2013 survey producers “have room to grow” through yield improvements. What is not in dispute is that the medical product market has changed since that 2013 survey. While dried flower was the main source of the medical product given to patients, the medical products have change in form and variety and DOH has not accounted for the change in the market.

7. In essence, DOH is using its regulatory authority in a manner and with an end toward impeding the purpose of the Act. Further, its regulatory mandate of 450 plants is not based on fact or reliable data and is not rationally related to its regulatory authority. More importantly, it impedes the ability to assure medical patients have an adequate supply.

UNCONTROVERTED FACTS:

The following facts are established by admissions in the pleadings or by stipulation of counsel at the pretrial conference:

1. The Department of Health commissioned a survey of patients enrolled in the Medical Cannabis Program in 2013.
2. Prior to February 27, 2015, licensed non-profit producers were limited to 150 cannabis plants.
3. A change to NMAC 7.34.4.8 went into effect on February 27, 2015, which limited licensed non-profit producers to 450 cannabis plants.
4. There are currently 35 entities which are licensed by DOH to be non-profit producers.

FINDINGS OF FACT:

1. DOH's choice of 450 plants as the limitation point is not based on reliable data or updated data. DOH's choice of 450 plants is not supported by current and/or reliable data and is not justified by any grant or delegation of authority by the New Mexico Legislature.
2. Evidence at trial showed exactly why "regulated" lacks an "intelligible principal" and presents such a danger of exceeding a statutory mandate. Department Secretary Lynn Gallagher said the "state is tasked with regulating a program in a strict manner" (260:17-19) and DOH operates the "program in a rigid, strict manner" (327:13-15). DOH impermissibly reads into the statute its style of regulation that in fact impedes on its statutory mandate to ensure an adequate supply.
3. Dr. Kelly O'Donnell concluded that a rational, reasoned forecast of demand outstrips a reasonable calculation of supply from non-profit producers by several hundred percent (404:25-405:4, 418:10-15, 421:7-11).

4. Dr. O'Donnell also testified that the shortfall could not be made up by production by personal production licensees or by producers using all of their production capacity (418:10-15). Furthermore, demand will only increase in the future due to rising patient enrollment and demand for diverse products (378:18-21, 386:15-19, 391:5-8, 393:25-394:4). There is also "pent-up" demand from patients who are not enrolled in the program precisely *because* they do not have access to medicine, and this demand is essentially silent (415:3-24).

5. Plaintiff Nicole Sena cannot obtain a beneficial-use product from a regulated, intrastate source. She can only obtain "beneficial use" from an unregulated store and an interstate source: shipment from a producer in Colorado to the CBD Boutique (109:1-25). That store is not on the list of DOH-licensed dispensaries at Exhibit O. She cannot even find a "generic" (versus the branded Hayleigh's Hope) 20:1 ratio CBD oil from a New Mexico producer (129-2-5).

6. Defendants offered no reliable evidence that regulated sources of cannabis provide enough medicine to meet patient needs. Since its 2013 survey, DOH has only gathered data on total yields, self-reported by producers. Further, these reports are not reliable (252:6-8, 252:19-22, 528:9-11, 547:2-7, 551:15-18, 571:20-23, 572:1-3, 688:8-13). DOH admits producers do not all report the same thing (709:1-6).

7. Equally important is what DOH has not done in three-and-a-half years: no more surveys, no studies, no calculations by epidemiologists or economists, no forecast reports, no projections (28:23-25, 32:6-8, 32:14-15, 216:22-25, 224:10-12, 225:22-25, 226:1-4, 229:9-12, 231:18-21, 242:7-11, 248:18-22, 250:3-7, 252:23-253:1, 515:5-19, 524:15-17, 527:15-22).

8. DOH has not done enough to gather and learn from data about patient use.

9. DOH's own data clearly show there is insufficient supply based on "beneficial use" or "adequate supply" figures. For example, DOH's Exhibit R says that in the first quarter of

2017, licensed producers yielded 2,353,858 units, for an average of 196,155 units per week. Even in the best possible scenario, 196,155 divided by 45,000 patients equals 4.36 units per patient per week. 4.36 units is less than half of the 9-10 gram average weekly consumption reported by patients in DOH's 2013 survey [Exhibit 6] and found in Dr. O'Donnell's research (79:10-11, 363:14-364:4).

10. There is no connection between 450 plants and risk of diversion/Federal interference. The DOH provided no evidence that the risk of federal interference with the medical cannabis program is related in any way to its 450-plant limitation.

11. Furthermore, Defendants presented no evidence or explanation as to why 450 is the magic number at which the risk of diversion is eliminated or significantly decreased.

12. Defendants presented no evidence or explanation that the risk of diversion becomes imminent when producers have 451 plants, but is not imminent when producers have 449 plants. Likewise, Defendants presented no evidence or explanation that the risk of federal intervention becomes a clear and present danger at 451 plants, but not at 449 (see 800:23-801:1).

13. Defendants' basis for the 450-plant limitation is reduced to the position "the 2013 survey said producer supply was only one-fifth of patient consumption, so we multiplied the number of plants by five" (223:1-6, 290:15-19, 534:22-25). The problem is DOH's calculation did not account for future patient growth, which was known to DOH at the time.

14. DOH failed to implement a proactive system of medical cannabis regulation. DOH reactively responded to a shortage crisis in 2013, but it reacted only to the needs of the existing 9,760 patients. A regulation designed to serve 9,760 patients cannot reasonably be expected to serve 45,000 patients, and the data used to serve 9,760 patients may not be used by hope of higher yield to serve 45,000.

15. Plaintiffs have met their burden.

16. The Plant-Count Limitation Effectively Overrules the Statute. The trial evidence established that DOH's 450-plant limitation overrules the statute because it prevents patients from obtaining sufficient amounts of cannabis from *regulated sources*. The Court itself asked several times how the 450-plant cap accomplishes the purpose of the statute (281:16-22, 561:1-4, 570:22-517:1, 784:15-17). Defense witnesses failed to offer satisfactory answers to the Court's pertinent question and thus failed to justify the existence of the 450-plant limitation.

17. While DOH commissioned a patient survey in 2013, the survey results reported numbers representing projected per-patient "need" and the total global projected amount of cannabis which would be required to meet this need. This survey has not been updated since its creation and its undisputed findings do not correlate to the current patient population.

18. DOH has not revisited the 450 plant count limitation since 2014, even as the patient enrollment in the Medical Cannabis Program continues to grow. DOH has defended the figure and has claimed that 450 plants-per-producer is currently meeting patient needs. The data collected and compiled by DOH is irregular, arbitrary and inaccurate. Plaintiffs claim that DOH is incapable of data-driven decisions is not substantiated. Deference is due to DOH to develop a data-drawn decision. However, DOH's defense of the 450 plant count is not justified based on any data source it currently employs or the plant count it has promulgated by rule.

19. DOH has not conducted another survey since 2013. Exhibit 6

A. It has not surveyed patients.

B. It has not surveyed physicians.

20. It did not take into account how patient enrollment would increase over the years.

21. Exhibit 12 shows patient growth has expanded from the date of the last data assessment (2013) indicating patient numbers have increased from 10,708 to 29,165 as calculated in 2016.

22. Exhibit 18 indicates the Department of Health promised to “have a plan to meet current and future patient needs. Despite this 2014 promise, the Department of Health has not conducted a survey or otherwise assessed patient needs on updated data.

FINDINGS OF FACT BY WITNESS TESTIMONY

The Court here outlines additional findings by witness testimony, followed by the witnesses trial testimony.

NICOLE SENA

1. Testified as a caring and thoughtful mother whose daughter has a rare form of epilepsy requiring medication for the treatment of severe seizures.

2. Traveled to and remained in Denver for 6 months to treat her daughter for the life threatening ailments involving the seizure disorder.

3. Indicated that she used CBD oil. She found that CBD oil assisted in the treatment of her daughter’s seizure disorder. After use of CBD oil, her daughter is free from seizures and is able to reach milestones. CBD oil requires a lot of plant material and, relevant to the Court’s decision, was not contemplated when DOH conducted its survey and tied the 450 plant limit to the adequate supply.

4. Obtained CBD oil or Haley’s Hope. She went to Ultra Health to obtain Haley’s Hope. Ultra Health indicated it did not produce enough plants to create CBD oil or Haley’s Hope. It is clear that if Ultra Health has the plant product available to it, it would produce a CBD oil similar to Haley’s Hope.

5. Established standing that the absence of medical marijuana production may injure her child. She testified she wished to work with Ultra Health to develop this oil.

6. The Court finds Plaintiff Nicole Sena has standing to bring this claim, as she does not have access to Haley's Hope.

7. She can order the product on-line, however she is concerned about the quality.

8. It is not disputed that a product like Haley's Hope, because it is complex, takes more plants to produce. A producer is not going to use 50 of the 450 plant limit to produce 2 ounces of CBD oil.

Q. Good afternoon. Can you please, just once more, state your name for the record.

A. Nicole Sena.

Q. Where do you currently live?

A. In Los Lunas.

Q. And do you have any children?

A. Yes.

Q. How many?

A. I have two.

Q. Okay. And boys, girls?

A. Both girls.

Q. And what ages are they?

A. 3 and 20 months.

Q. And so your younger daughter is 20 months?

A. Yes.

Q. Do you feel comfortable sharing her name here today?

A. Yes. Her name is Amylea Munoz.

Q. Does Amylea face any health challenges?

A. Many.

Q. And what kind of health challenges?

A. Amelia has a rare form type of epilepsy.

Q. And did you discover treatment that changed that prognosis?

A. Yes. Yes, I did.

Q. What was that?

A. CBD oil.

Q. Okay. How did you discover that?

A. By research online. I had brought it up to the medical team a few times. They had told me that they had used it for other patients, but the only reason why they used it was that they used it in an outpatient setting.

Q. And so how old was -- did you eventually try treating Amylea with CBD oil?

A. Yes. Go ahead.

Q. I just wanted to clarify. What is your understanding of what CBD oil is?

A. It's a cannabidiol oil.

Q. And which one did you talk to?

A. With Ultra Health.

Q. Okay. And when was that?

A. A long time ago. I think it was not too long after I had come back from Colorado.

Q. And was Ultra Health able to provide you with the Haleigh's Hope oil?

A. No.

Q. So when you go to the CBD Boutique, is there always a guarantee that Haleigh's Hope is going to be there on the shelf?

A. No.

Q. And do you have to make any special arrangements with CBD Boutique to get it?

A. I usually go about two weeks ahead of time before she runs out of her oil, just to make sure that I have a bottle on hand. There has been times that I have gone to CBD Boutique where they just don't have it, and they won't be getting it in until the following week.

Q. And what's the impact on your life when CBD Boutique doesn't have any on the shelf?

A. It's scary.

Q. And does it add to the stress -- does it create stress in your life?

A. Yes. If Amylea doesn't have her medicine, you know, she will be seizing. We'll end up in the hospital. We'll be Life Flighted to Denver again. We'll have to start all over getting her back in control. It's very hard to get her under control when she has a breakthrough of strong tonic-clonic seizures.

Q. And where is CBD Boutique?

A. They have one in Nob Hill and then one on the west side.

LEIGH JENKE

1. Leigh Jenke testified she is employed by Ultra Health.
2. She is the Director of Operations for Ultra Health.
3. Because of plant limit, she is not able to provide the type of medication requested by the patient.
4. She testified that 50 plants would be required to produce the needed amount of Haleigh's Hope.

5. She testified that she would need 50 plants (4 strains by 12 months). They would not be able to serve other clients or other patients.

6. Jenke established that the patient demand and medical needs have changed since the 2013 survey upon which Defendant relies for its 450 plant count limit. As such, the additional plant count limit does not correlate to the ongoing requests of the statute.

Q. Would you please state your name for the record.

A. My name is Leigh Jenke.

Q. And what is your current employer?

A. Ultra Health. NMTO - Ultra Health.

Q. Okay. That's -- what does "NMTO" stand for?

A. That's New Mexico Top Organics, and the LNPP under management of Ultra Health.

Q. Okay. And is there any kind of a trend that you're seeing in the types of products that patients are asking for? Are they, for example, mostly satisfied to stay with dried flower or are they starting to ask for other types of products?

A. Well, with our -- I guess with the more sophisticated methods of making product, you see a wider variety of product that patients want. So we started out with the smokeable cannabis, the smokeable flower, and then, you know, it's kind of morphed into edibles, and then oils, and you know, we're starting to see a really really big trend in HNB products which are -- they're heat-not-burn. And so these are concentrates and different things that unfortunately they're probably a little bit better for patients not to have to smoke just the dried flower. But to make these products, it takes higher plant material.

Q. So is it correct, sounds like the lowest amount of plant material for a given product would be dried flower?

A. Yes.

9. Distributors are limited in supply by the plant count.

Q. Okay. Are there any types of products that Ultra Health has had to limit in terms of what it's able to sell to patients?

A. We don't actually limit ourselves. We don't limit our products. But we are limited by our plant count. We can only -- we can only harvest -- we only have 450 plants. And that includes the really tiny baby seedlings to the flowering plants, plus the male plants. So we can only harvest about 60 plants every harvest. So that limits us in the amount of products that we can put on the shelves.

10. Jenke established that the only option they have to meet the supply demanded is to purchase it on the wholesale market and that is not reliable. Jenke also established that the outdated plant limit does not take into account the medical delivery system for the medicine, for example dry flowers versus oil.

Q. So you have to decide what percentage of that harvest is going to go to dried flower, that percentage is going to go to oils, what percentage is going to go to some other form?

A. Yes.

THE COURT:

Let me ask you. With regard to the testimony I just heard, could you buy the -- in order to create Haleigh's Hope, could you buy the product wholesale and then produce the oil?

A. THE WITNESS: We wouldn't be able to produce the oil ourselves. The Haleigh's Hope, if -- I suppose, if we found another LNPP who was willing to grow those four plants, we technically could. But I think one, you know, some of the LNPPs, they don't all grow 450 plants. And unfortunately, using those four plants, it would be roughly 50 plants a year out of the 450 plant

count. So if they were willing to donate that many plants for just -- for just Ms. Sena, then yes, we could do that.

THE COURT: So the wholesale has to come from someone else in New Mexico?

A. THE WITNESS: Yes.

Q. So you're not able to provide Haleigh's Hope to Ms. Sena or to Amylea. And I think you just said it would be 50 plants have to be dedicated all year in order to be able to produce that one product?

A. Right. 50 out of our 450, and I'm sorry, but just for Amylea.

DUKE RODRIGUEZ

1. Authorized to grow 450 plants from seeding to flowing plant.
2. Of the 35 producers, 26 of them have renewed at 450 plants. The remaining have not paid a license to produce the full 450 plants.
3. The least expensive product is the dried flower. As the product gets more complex, the more plant material is required.
4. Testified that the concentrations are getting higher, and the flower is taking less of a share. That said, the total demand is increasing.
5. Duke Rodriguez established even in the rotating manufacturing process 450 plants do not correlate to adequate supply.

Q. Good afternoon.

A. Good afternoon.

Q. Would you please tell the court your name.

A. I am Duke Rodriguez.

Q. Okay. And what is your current employment?

A. I am the CEO/President of Ultra Health, LLC, based in Arizona.

Q. Okay. And you're, of course, aware of an entity in New Mexico, a nonprofit corporation, New Mexico Top Organics - Ultra Health, Inc.?

A. Yes, sir.

Q. What is the relationship between Ultra Health, LLC, and the nonprofit corporation in New Mexico?

A. We are the management company

Q. How many plants is Ultra Health able to harvest each year, if you know?

A. We have 450 licensed plants, and we do them in a perpetual cycle so we can have as much of a stable inventory as you can have with 450 plants. So we take down about 60 to 70 plants every two weeks. So 450 plants, that's your maximum you can ever have on the ground. But because of the perpetual system, you harvest somewhere between 13- and 1,400 plants a year.

Q. Okay. And do you know whether or not the ability to harvest 13- to 1,400 plants a year, based on 450 licenses, is that typical in New Mexico?

A. We certainly talk to all producers to see what the growth style was here. You can harvest plants on three-week cycles, five-week cycles. But it seemed to be the industry standard that eight weeks of flower and eight weeks of veg is about the right standard. From our own experience, we use normally a lower cycle in other states, five weeks and five weeks. We found that eight weeks on flower and eight weeks of veg seemed to be the right cycle.

6. Duke Rodriguez established the large increase in patient enrollment.

Q. Okay. And we'll come to it in a minute, but currently, right now, do you know roughly how many plants there are per patient today in New Mexico?

A. Currently, with the reenrollment effect of August 1, I believe that reenrollment was around 15,350 plants were relicensed since August 1, plus or minus 700, August 1, 2017, which will carry through July 31, 2018, which is up from the previous year of 13,800. So you have 14,350 plants licensed for currently, as the Secretary has testified, Secretary testified, 45,441 cardholders.

Q. Does that come up to about .35 plants, give or take?

A. Comes to about one-third of a single plant per patient.

7. Compared to other States, the count limit is an outdated concept.

Q. In Colorado, are you familiar with its Medical Cannabis Program?

A. I am.

Q. Can you tell the Court their ratio in Colorado for plants per patient?

A. The Colorado Medical Cannabis Program, not counting the adult use program, has it in statute at about -- it's exactly at -- it's allowed up to six plants per enrollee. So they have got just about 100,000 cardholders, so they are currently allowing about 600,000 plants with their medical plan.

THE COURT: Okay. But the Colorado amount that's set by statute, is that what is defined as reasonable access by statute, or is it the same math you just went through with me? That those are the plants in production available to patients in Colorado? Do you see the difference?

THE WITNESS: That's a good question. The six plants is defined in statute. Then they have to allow the growers to subscribe how many plants they want to grow. The program is capped at six plants per enrollee. So they can always move up and down as enrollee goes up. In fact, the number of plants that are actually in production, they report the number of plants that are in production by month. And their number of plants in production for the last 12 months has been balancing between about 300,000 and some change and 312,000, in that range. So we've watched

their utilization rate and their utilization rate on a per patient, per plant, is right at three plants per enrollee.

THE COURT: So compared to ours, you would describe the one-third as a utilization rate?

THE WITNESS: So I would say it was about a ten-fold difference, that's correct.

8. Secretary Gallagher has in good faith attempted to continue production diversion of the medical product and protect the State from federal intervention given the limited resources provided to her agency.

SECRETARY LYNN GALLAGHER

1. Joined Department of Health in 2012.
2. Appointed in 2016; confirmed by the NM Senate.
3. Testified as to Exhibit 6:
4. The direct of this witness was informative because it inquired as to whether DOH could change to license for more than 450 plants and could use that money to regulate the production.

Q. Good morning, Secretary. Can you just state your name one more time for the record.

A. Lynn Gallagher.

Q. And you joined the Department of Health in August 2013; is that right?

A. Correct.

Q. And at that time, you joined as a Deputy Cabinet Secretary?

A. Yes.

Q. And what were your duties as Deputy Cabinet Secretary?

A. I had oversight authority over a number of programs within the Department. I also worked directly with the Cabinet Secretary on various strategic plan initiatives and overall running of the agency.

Q. Now could you look at Exhibit 18. And Exhibit 18, is that a release or a letter from the Department of Health?

A. It's a press release from the Department of Health, yes.

Q. Okay. From February 2014?

A. Correct.

Q. Okay. And it states, "The New Mexico Department of Health announced proposed adjustments to the Medical Cannabis Program regulations." And it goes on, "The Department is proposing to increase plant limit from 150 total plants and seedlings up to 150 mature plants and up to 300 seedlings. This will require a rule change and public comment before implementation.

The Department plans to open the applications period to add up to 12 licensed nonprofit producers. There are currently 23 licensed nonprofit producers"; is that right?

A. Yes.

Q. And at some point during the rule making, the proposed rule was amended to 450 plants, regardless of maturity; is that right?

A. Yes.

Q. And then the rule was finally published and finalized in February 2015; is that right?

A. Yes.

5. DOH's argument regarding resources is credible; however, the Secretary acknowledges that diversion can be mitigated even if a higher plant count is permitted.

Q. Now, the Department charges different licensing fees according to how many plants a producer wishes to possess; is that right?

A. Correct.

6. That is, DOH showed no nexus between plant count, enforcement or diversion.

Q. So it's, I believe, 30,000, which is for 300 plants, and then the total for 450 plants would be a 90,000 licensing fee; is that right?

A. Correct.

Q. Are you aware of any reasons why the Department could not charge an even greater licensing fee for more than 450 plants?

A. A number of factors would go into that consideration

Q. I'm sorry. Let me begin again, then. Interrogatory 2 asked, "State the complete basis for your determination that each New Mexico licensed nonprofit producer should be allowed to grow no more than 450 plants." Is that what Interrogatory 2 asked?

A. Yes.

Q. Now, there's -- I just want to point your attention to there's a lengthy objection there, and going to exhibit -- sorry, page 4, the third line down, the answer is, "Cannabis is identified as a Schedule 1 drug in the U.S. Controlled Substances Act, and as such a conflict exists between state and federal laws concerning the use and possession of cannabis within a Medical Cannabis Program." Do you agree that the federal status of cannabis was a factor in the Department's decision to implement a 450-plant count limitation?

A. Yes.

Q. If you could look at Plaintiffs' Exhibit 23. Just one moment. Sorry. Plaintiffs' Exhibit 22. I just want to make sure I have -- can you describe what Plaintiffs' Exhibit 22 is?

A. It's an interrogatory.

7. The 450 plant count is based on regulatory needs and not based on the medical or data assessment of patient needs.

Q. When DOH implemented the 450-plant count rule, did it consult the medical advisory board for the board's opinion on the appropriate level of supply that was needed?

A. It did.

Q. And what did the board say?

A. I don't recall, at this time.

Q. Could you turn to Plaintiffs' Exhibit 24. And this is titled "Report and Recommendations to the New Mexico Department of Health from a Public Hearing on Monday, August 25, 2014 at the Harold Runnels Building;" is that right?

A. Yes.

Q. And did you attend that meeting?

A. No.

Q. Did you receive this report that was directed to the New Mexico Secretary of Health? Or did you look at it? Ever?

A. I've looked at it, yes.

Q. And if you could look at exhibit -- I mean sorry, page 4 of Exhibit 24. No. 2, "Changes in the Definition of Adequate Supply. Dr. Jenison recommends NMDOH withdraw a proposed rule change mandate that medical cannabis be obtained only from intrastate and licensed sources, especially given NMDOH's failure to keep up with demand for medical cannabis." Were you aware that the medical advisory board identified a failure to keep up with demand in August 16 2014?

A. I was aware that Dr. Jenison held that opinion.

Q. And after this meeting, what did you do to follow up with Dr. Jenison to find out the basis for his opinion?

A. He had a meeting with Secretary Ward, myself and Brad McGrath.

Q. And at that time, did DOH make any changes to its proposal to move the limitation to 450 plants?

A. It was among the factors we considered.

Q. So DOH originally proposed the 450 number in February 2014; is that right?

A. Actually, we originally proposed a bifurcated system with the 150 and then 300 seedlings. In my mind, they're distinct and different.

Q. Did you request any number from Dr. Jenison as to what he believed should be the supply figure?

A. We had a lengthy discussion with him about what he considered to be sufficient to meet the needs in 2013.

Q. And after meeting with --

A. '14, sorry.

8. After the 2013 study the plant count limit was amended from 150 to 450 plants without distinction as to their maturity.

Q. After meeting with Dr. Jenison, did DOH make any further changes to its proposal for 450 plants?

A. I don't recall.

THE COURT: Can you remind me again when it was moved from 150 to 450?

MS. CAFFREY: The original proposal was February 2014. That's Exhibit 18. And during July 2014, it was slightly amended so that it was 450 without distinction to the maturity of the plant.

THE COURT: Okay. So it would have been after this 2013 study?

MS. CAFFREY: Correct.

THE COURT: Okay.

9. Simple extrapolation of increase of potential numbers multiplied by DOH's current accepted grams per patient need shows the current plant limit is inadequate.

Q. The survey says with 9,760 patients, to satisfy patient need, supply would need to be approximately 5 million grams per year. So using the logic of the survey report, wouldn't it make sense that if approximately 10,000 patients needed 5 million grams per year, according to the survey report, wouldn't it make sense that 40,000 patients would need approximately 20 million grams per year?

A. Not necessarily, no.

10. Further, DOH never went back and duplicated the survey.

Q. And DOH never went back and did any other surveys of any patients, did it?

A. Not yet, no.

Q. And DOH did not in 2013 say, "We haven't surveyed enough patients, let's go survey more"?

A. It was a consideration.

Q. But there have been no other surveys so far?

A. Correct.

Q. And DOH has made no other studies or projections of how much cannabis all the patients in New Mexico would need, has it?

A. We did a different study through our Epidemiology and Response Division.

Q. And do we have that here today?

A. I don't, no.

Q. But the 2013 study is the only patient survey DOH has done?

A. Correct.

11. Such data inadequacies include the lack of an epidemiologist's study.

Q. And in 2014 -- sorry, 2014, none of DOH's epidemiologists produced a formal opinion about what the level of plants should be, did they?

A. Not that I know of. I don't understand the question, but not that I know of.

Q. Let me ask it in a forward way. Did any of DOH's epidemiologists make a formal recommendation about the number of plants which should be allowed?

A. No.

Q. So you cannot say today, between 2014 and the present, what the growth rate of patient enrollment is?

A. I could if I had a calculator and the actual numbers in front of me. I mean, I could add it up and divide it by --

Q. Oh. But you have not done that?

A. It's not something I would do.

Q. And you have not charged any other employee at DOH with calculating that growth rate?

A. So I don't charge people with doing anything, but I have not asked anyone to do that, specifically.

12. It is not disputed patient enrollment has increased significantly.

Q. And prior to the Kieve case, which sped up the enrollment for patients with PTSD or chronic pain, was the patient enrollment rate constant or accelerating?

A. It was -- it was growing, but it was growing at a consistent level.

Q. And who made that calculation of whether it was growing at a consistent level?

A. I think you could look at the numbers and say it was growing at a consistent level.

Q. And did you actually do that?

A. I personally did not do those additions.

Q. Did you instruct any other employee of DOH to do that?

A. No, I did not.

Q. And after the Kieve case, was the patient enrollment rate constant, or accelerating, or decelerated?

A. Can you repeat that?

Q. Sure. After the Kieve case, which again, made it easier for patients with PTSD and chronic pain to enroll, did the patient enrollment rate decrease, increase, stay the same?

A. So immediately after the change in the rule, which happened as a result of the Kieve decision, enrollment, patient enrollment spiked dramatically, and at that spike, has continued a steady growth upward.

Q. And so even after the Kieve case, in the months afterward, patient enrollment continued to increase?

A. At a steady level, yes.

Q. And in fact, in the, let's say, first two quarters of 2017, patient enrollment has continued to increase?

A. I'm not familiar with the exact numbers, but I would venture a guess at saying probably they increased. We've had some decreases in patients. We've had some patients opt out of the program for various reasons.

Q. Whose responsibility is it at DOH to calculate patient growth rates?

A. So the Medical Cannabis Program itself is tasked with managing the program. Part of those duties include enhancing the program and looking at trends of information. We don't have a named person who right now is tasked with doing anything. Everybody's tasked with managing and regulating the program.

Q. And how many times in the last year has any employee of the Department of Health come to you and said, "This is the patient enrollment rate," how it's moving?

A. So on occasion I've met with the director, Kenny Vigil, and we've talked about what the numbers in the program are, based on the quarterly reports.

Q. How many times do you have that discussion per month?

A. We probably meet once a month. Sometimes there are reasons to meet in between. So I would say in 2017, we've probably met ten times, and five of them talked about trends in the program and what the producers were reporting to the Department.

Q. How many times has Mr. Vigil given you a percentage as to the patient enrollment growth rate?

A. He has not.

Q. And how often have you requested that the patient enrollment rate be given to you in a percentage?

A. It's not something I would request specifically.

Q. How many hours have you spent consulting or just talking with agencies in other states regarding how they manage medical cannabis?

A. Oh, boy. In hours?

Q. Yes.

A. 30, over the course of my four and a half, four years at the Department.

Q. So 30 hours over four and a half years. So that's what, seven and a half hours per year?

A. I guess.

Q. Have you asked any employee of the Department of Health to calculate a rate of increased productivity?

A. I have not.

Q. Have you tasked any employee of DOH with calculating how patient growth percentages would affect demand?

A. No.

13. The 450 plant limit is based solely on the regulatory authority of the Secretary. Even then, there is no shown nexus between that number and DOH's ability to regulate distributors. Most significantly, the limit restricts adequate supply. The Court inquired directly into this subject matter.

THE COURT: Where, as a Secretary, do you believe you derive your authority to institute a cap?

THE WITNESS: A number of places. I would say the over- -- in an overall general term, in a regulated system means just that, regulation -- regulatory system means establishing guidelines and protocols to ensure for the beneficial use of cannabis. But I also think, from my personal perspective, that also when the legislature decided to place a possession limit --

THE COURT: Okay.

THE WITNESS: -- that has to create a requirement on the Department to set forth certain guidelines of how that possession limit is satisfied.

THE COURT: Okay. So let's start with that. Tell me how you view the cap, a 450-plant cap. How does that correlate to the possession unit for the individual users, as part of your duties to regulate?

THE WITNESS: So we know -- we knew at the time, or when I was involved at the time with the current ten-plus thousand people in the program, and they had, at that time, a possession limit which was different. It was lower. It was a different possession limit that -- it described a certain amount that patients could, up to could, possess.

THE COURT: Right.

THE WITNESS: But we also know that the information that's given to us not only from producers, but from patients, is not always a hundred percent spot on. So we know that there are deviations in those possession actuals, for lack of a better word.

THE COURT: Okay.

THE WITNESS: So a patient can possess in a 90-day time period up to 230 units, currently. But many patients use -- need a very, very small amount of a tincture or an oil to satisfy their chronic pain, or their Parkinson's disease, or whatever it is. I'm not a provider, so I don't want to speak about the mechanics of the medicinal part. But we know that in regulating the program, we have to establish those criteria, and understanding that it's an ebb and flow. There are also times when patients, through their provider, hopefully with the consultation of their provider, become almost -- not immune, but their tolerance level increases. And sometimes it's important for them to take a time out from utilizing cannabis to give their body time to sort of reset, and then they go back and they have a different -- I don't want to call it a possession. A need, a need for the patient. The

possession limit is a term of art, right? The statute has to say you're protected if you are within these limits. But for a patient, and with the exception in place, sometimes they need more, but sometimes they need very little. And in order for us to determine that, it's not an easy thing to do, based on a number of different factors. And so we do what we always do as a regulatory body, is we establish parameters and then we make sure that they're working. And then if we need to adjust, we 11 embark on a discussion and make a determination to adjust. In 2013, the agency was receiving a lot of correspondence and calls about patients not being able to access product and their medicine. We're not receiving those calls and concerns today. In 2013, people were accessing the black market. It didn't just start -- black market product didn't just start in New Mexico when we raised the plant count. Or maybe it did. But people were accessing the black market then and they were still in droves contacting the agency saying, "We need medicine and we're not able to get it, and our producer is closed. We can't go in and get it at a distribution site." Someone said there needs to be a survey, so they did the survey. We're not having calls, we're not seeing people, and the self-reporting producers are showing that they have supply in stock, as a carryover, based on the sales of what people are buying from them.

THE COURT: And that I understand completely, because that part -- what is clear about the statute is it really comes in at the, let's say the user level, right? Although patient level. Although, what is the term? Reasonable supply.

THE WITNESS: Adequate supply.

THE COURT: Adequate supply is mushy. But at least there's a definition there. There's nothing in the act about the distributor, the manufacturer level, other than sort of safe and secure facilities, that kind of stuff. So I guess my question is, how, given what you've just said, how does that tie -- if I were to say what is the reasonable purpose for DOH to have a cap, to do

exactly what you just said, which is entirely reasonable, but what is it about the cap that makes -- is a reasonable regulation to affect what you just described? Because what it sounds like is the 150 cap triggered these responses you got in 2013. We have this 150 cap, the patients are saying because of the cap, I can't get an adequate supply. So you bump the cap up. But I need to know from you what is the reasonable, justifiable purpose of that regulation to affect what your job is with regard to adequate supply?

THE WITNESS: Because I think that the two have to -- the two have to operate together. Producers, manufacturers, couriers, have to abide by the Lynn and Erin Compassionate Use Act, circularly. So that's a broad statement. But in and of itself, the fact of establishing an adequate supply level mandates that we establish the guidelines for product being available to patients. It's not like patients have access to the medical -- through the Medical Cannabis Program, and can get it from anywhere, at any CBD Boutique anywhere, wherever they want to get.

THE COURT: Right.

THE WITNESS: They get it. It has to be regulated, because in my opinion, the legislature understands that it is medicine and it's not recreational, and that there's a distinction. And in order to regulate it, the regulator, which was granted in the statute to the Secretary of Health --

THE COURT: Right.

THE WITNESS: -- is to make sure that that is held in a high regard. And I don't think that having absence of language dictates the requirement to ensure that producers have an amount that can be regulated.

THE COURT: Okay. Looking back at the way the new cap was created back before with the hearing officer, seems to me it was sent to the hearing officer, the hearing officer had questions for the Department, and I guess e-mailed -- kind of unusual, quite frankly, okay, having done

this. But it is what it is and it is what the record is. In the record that you've reviewed, is there that conversation or is that a deliberation by the hearing officer as to when we go to 150 to 450, here's going to be the impact on our regulatory concern that the feds are going to come in, shut down a major producer and cause a huge supply challenge? Do you know if that was considered?

14. The 450 plant count does not meet a fundamental purpose of the Act, because it impedes DOH's obligation to ensure adequate supply.

THE COURT: Give me an understanding of the data, of the hard data that the Department has. So if the part of the analysis in this case is whether or not the Department's determination that a 450-plant count, for the reasons we described, also meets a fundamental purpose of the act, which is to provide an adequate supply for patients; right? That's really what the proponent in the act is. I don't think you can dispute that. The hard data that the Department has is, is they will know how many patients are enrolled on a quarterly basis?

THE WITNESS: We know how many patients are enrolled, and I do believe we present that quarterly, yes.

THE COURT: Okay. And you know how many – you know the total plant count in the state, based on those 35 producers?

THE WITNESS: Yes. That are barcode – that are tagged, yes.

THE COURT: You don't know what stage those plants are in, necessarily, or do you?

THE WITNESS: Correct, we do not know what stage they are in.

THE COURT: And you do not know, outside of what they self-report, what the yield of those plants are?

THE WITNESS: Correct.

THE COURT: Would you know whether there is a huge variance in yield between a manufacturer?

THE WITNESS: I don't really know how to answer that because the yield is really hard to determine. It's what each producer considers in its yield. There's trim. You know, do they consider trim as part of the yield? Do they not? Do they use some of the leaves and things for juicing and other things? I mean, there's -- it's not -- yield is a very hard calculation to determine --

THE COURT: Okay.

THE WITNESS: -- with any efficacy.

THE COURT: It would be a hard data point to be fixed with a little variable. So it depends on what the manufacturer does with the plant.

THE WITNESS: Kind of. You know, they have to -- hopefully, they're all measuring yield before -- you know, before they test or when they test, they're doing all of that. And then they're sending things off for various purposes.

THE COURT: Hold on. (Discussion off the record.)

THE COURT: Did you have anything to add?

THE WITNESS: Just that I think there are probably better ways, and we're moving toward those better ways, but based on the program that we have today, pinpointing exactly how much a producer yields --

15. DOH's answer to adequate supply is to hope yields increase on a static plant number that is based on 2013 data. That is not sufficient.

THE COURT: The reason I asked these questions is because I'm wondering why the Department since that -- whatever flaws may exist in this 2013 survey, there are some data points in there

that are -- seem to be more objective. Tell me if I'm misunderstanding, because I need to understand this. It seems to me the Department is saying we don't know if there is an adequate supply unless patients come to us and say there is a shortage. Then we'll trigger the process. Rather than going back to another 2013 survey and saying let's see how many patients are out there, plants. Let's make this data driven rather than communications from patients that are just reporting we don't have an adequate supply.

THE WITNESS: And that's something that we're working on. That's part of why we, a little bit more than a year ago, brought on a seed to sale software program. I mean, these are some of the things that we're engaged in right now, because we know that when the program started in 2008, it was very rudimentary and it was very malleable. But in 2013, we did see a spike in communication. That in and of itself is not the only thing that I would consider as my baseline for when I would embark on another decision. But I do want to say that I get just as many people telling me that there is not a shortage, and that patients are accessing medicine, and this is just about profits. And I weigh them anecdotally like I weigh everything else. So how do I appease -- I'll say the same thing that I've said over and over again. I said it in settlement negotiations, that this is a balance. And --

DR. KELLY O'DONNELL

1. Dr. O'Donnell is a reliable expert who established that by basic economic principles DOH's adequate supply analysis is flawed.

Q. Dr. O'Donnell, will you please state your name for the record.

A. Kelly O'Donnell.

Q. Okay. And how are you employed, currently?

A. I am an assistant research professor at the School of Public Administration at the University of New Mexico, and I'm a private economic consultant.

Q. Okay. You've been offered as an expert in economics. Do you claim to have any expertise with respect to agriculture or any expertise specific to the Medical Cannabis Program outside of an economic background?

A. The expertise I've gained through research in the last year on the cannabis program, I would consider myself to have a fair degree of expertise. I'm also an expert in the New Mexico's economy and in healthcare in New Mexico.

Q. Are you able to forecast -- are you able to use your knowledge, skills and expertise as a Ph.D. economist to evaluate the supply and demand of a product in New Mexico?

A. Yes.

Q. Would you be able to evaluate the supply and demand, if you were to be asked to do so, could you create a model for the supply and demand of Coca-Cola within the State of New Mexico?

A. Sure

Q. Okay. One last thing I want to ask you about. In preparing your report and looking at supply and demand in the state, did you review the 2013 survey that the Health Department conducted?

A. I did.

2. Dr. O'Donnell used the data available to her by DOH.

Q. Okay. And would you tell the Court about your review of that study.

A. Well, I mean, it was useful information, 13 certainly. I mean, there were a number of pieces of data developed from that survey that were of interest. One of the major -- the questions in that survey, some of them weren't phrased optimally --

Q. These are surveys that the Health Department sent to licensed patients?

A. Yes.

Q. Okay.

A. I think the most valuable piece of information was how much these licensed patients were reported consuming on a weekly basis and how much product they reported consuming on a weekly basis. The ultimate, you know, the analysis that the Department of Health did of the data that derived from the report wasn't as compelling because it was somewhat dated. But those data points about how much was being consumed by patients were very valuable.

3. Dr. O'Donnell provided reliable testimony that assisted the trier of fact.

THE COURT:

All right. Before the Court is the Department of Health's objection to the proffer of Dr. Donnell as an expert economist and in particular an expert with regard to medical supply and demand, or medical cannabis supply and demand. And in addition, the Department's objection to the introduction of what has been marked as Exhibit 7, which is the medical cannabis market in New Mexico, Kelly O'Donnell, Ph.D. It's dated August 16. Within that is layers, two layers. Namely one is the qualifications as Dr. O'Donnell as an expert.

But on that particular issue, if you can point to the portions of the report which either those are disclosed or she's qualified to testify, I'll reconsider that. But I imagine at this point, the scope of the testimony is as an economist. And if the underlying data is reliable, those opinions will be accepted for whatever weight I ultimately give them.

4. Dr. O'Donnell confirmed what is known: the patient population is increasing and a static 450 plant limit is not fundamentally tied to an adequate supply.

Q. Okay. We'll have some more questions here about the report, but in general, did you create – you said earlier you created a model to project patient demand in New Mexico. Will you please describe for the court what that model does and how you created it?

A. Well, the model is based on essentially the number of cardholders or people who are authorized to purchase medical cannabis and their likely consumption, or demand for cannabis relative to the supply that could be provided by a licensed producer, licensed nonprofit producers. And then, you know, obviously the deficit or the surplus is going to be the difference between those two numbers. Obviously, you take into consideration a number of factors in making that estimate. But those are the overarching, you know, those are the most essential components of the model.

Q. And so is it your expert opinion that as patients continue to participate in the program over time, the amount used per patient will increase? For each individual patient, not necessarily the average.

A. I can't speak to whether an individual patient's dosage will increase over the duration of their illness or whether new entrants to the program are more or less likely to consume more or less than the average. What I can tell you is that as the product mix evolves and diversifies, a shifting away from smoking flower cannabis towards products that are actually manufactured from cannabis will tend to increase the volume of cannabis used because those products per unit of potency take -- utilize more cannabis.

Q. Okay. So could you explain to me and to the court how you reached the conclusion that only 1.2 percent of the roughly 630,000 potentially eligible New Mexicans are participating in the program? Is it just simple math that about 30,000 -- how do you reach that number?

A. Well, you simply take the ratio of the number of participants in the Medical Cannabis Program, divided by the total population.

Why do you conclude that over time the rate of market penetration in New Mexico will increase over time?

A. There are -- the number one reason is that there has been, and continues to be, an increase in the number of cardholders, a marked increase. And so, I mean -- and the population of New Mexico is not growing that much and certainly not growing at the rate that the number of cardholders is growing.

Q. What did you conclude with regard to enrollment trends, taking into account the data change which you briefly touched on yesterday?

A. That the -- well, the number of folks enrolling in the Medical Cannabis Program was continuing to increase rapidly. That is one conclusion. The other -- the other data change was that the data reported by the Department of Health had changed. They had removed a number of cardholders from their count of cardholders. So at the same time that the population -- that more people were coming into the program, the Department of Health had made some database changes that dropped several thousand cards essentially out of the count of cards.

Q. And is that what we see in Figure 1 on Page 2, Dr. O'Donnell?

A. Yes.

Q. On Page 1 you have a subtitle, "Updated Cannabis Consumption Data." Would you -- from the Substance Abuse and Mental Health Services Administration. Would you please tell the court what conclusions or what information you present there?

A. That really simply speaks to the premise that there is greater cultural acceptance of cannabis in general. The National Survey of Drug Use and Health basically talks about the percentage of New Mexicans, or the percentage of people, who report having used cannabis recently. It also discusses their perception of cannabis as being risky. And essentially what the survey shows, not surprisingly, is a continued upward trend in the number of or the percentage of adults who consumed cannabis fairly regularly. And it also conveyed or showed that there was a decline in the percentage of adults who perceived cannabis use as highly risky.

Q. Okay. If you go back to Page 25 of your report, Figure 15, drawing your attention to the series of bar graphs with excess demand, given the 450-plant count limit imposed on licensed nonprofit producers by regulation, is there any way -- I'm asking you as an expert economist, expert in the medical cannabis market in New Mexico, is there any way for licensed nonprofit producers in New Mexico to meet patient demand while operating under the 450-plant count limit?

A. No.

Q. No way at all?

A. No.

Q. Even if all of the licensed nonprofit producers produced 450 plants?

A. Right.

KENNY VIGIL

1. Kenny Vigil operates the Medical Cannabis Program diligently and makes good faith efforts given the resources. He is a credible witness.

Q. Would you state your name and job title for the record, please.

A. Kenny Vigil, Medical Cannabis Program director.

Q. How long have you been the program director for the Medical Cannabis Program?

A. About a year.

Q. What did you do before becoming program director?

A. I worked for the Department of Health for four years as the public information officer.

Q. And what does your job as program director entail?

A. So I have oversight responsibilities of two divisions within the Medical Cannabis Program. One is patient services, where we administratively approve of patient applications and then there's licensing and compliance where we deal with the licensure and compliance issues of producers.

Q. How long has the Licensing and Compliance Division existed?

A. That's a fairly new division. I believe that it was staffed in April of 2016.

Q. Okay. The question on Exhibit U, you said to Mr. Woodward that you can't -- I think you said tally up how much is in stock. Is that with reference to the use of BioTrack?

A. Correct. So there's not a function that we can -- can't push a button and say calculate, just give me a total number.

2. Simply put, based on DOH's own numbers the 450 plant limit has no correlation to adequate supply and is an unsubstantiated number.

Q. Okay. I want to look at the -- let's take the -- let's take a number of a million. Let's see. Let's look at V-2, May 25 quarter. That's the first quarter of 2017 as reflected in V-2; correct?

A. Yes, sir.

Q. Okay. So if we were to take an even million -- I understand this is 1,159,000 in stock. But if we were to make it an even million, I calculate that that results in about 3/4 of an ounce per patient in the system, or about 17 grams. If you have a million grams, that's equal to 35,274 ounces, divided by 45,000 patients, you get .78 ounces. Does that sound -- I know we don't have a calculator, but does that seem like roughly reasonable to you?

A. I'll take your word for it.

Q. Okay. So a million grams is equal to about 17.16 grams per patient. That would also be 17.16 units; is that right?

A. Correct.

Q. Okay. And this, the Department has identified adequate supply for individual patients at 230 units.

A. Correct.

Q. Okay. So a million units in stock gets you a little bit less than 10 percent of adequate supply for each of the patients in the program.

A. That's assuming all of them are purchasing the max.

Q. No, that's assuming that each of them were to purchase an equal share of the stock.

MR. WOODWARD: Objection. Is there a question or is counsel just debating with the witness?

THE COURT: I think he asked whether it's 10 percent.

Q. So 17.16 units per patient is less than 10 percent of what the Medical Cannabis Program would consider to be adequate supply?

A. Yes.

Q. Okay. And on that basis of a million grams in stock, resulting in a little bit less than 10 percent adequate supply for each of the enrolled patients, that meets the Department or the Program's definition that supply is meeting demand?

A. Again, I think that we're assuming that patients purchase 230 units each quarter, or every 90 days, and we don't believe that to be true.

Q. But that wasn't my question. That amount would equal something less than 10 percent of adequate supply for --

A. Correct.

Q. And you think that that amount is sufficient to say that supply is meeting demand?

A. I do at this point.

3. Again the plant count is for regulatory purposes only and actually defeats the purpose of the Act by restricting adequate supply.

THE COURT: Okay. And the reason I ask these questions is because I'm still on this -- I'm going to ask you, as I asked the Secretary. Part of the litigation is over the 450-plant count limit. And if I were to ask you as the operator of the program -- because we've gone through this tracking database you have, and these quarterly reports, and complaints by patients -- what is it about the 450-count limit that, in your view, effectuates the purpose of the Compassionate Care Act.

THE WITNESS: Can you repeat that a little bit, maybe?

THE COURT: I basically asked the Secretary the same question. So if I understand, there was this 150-cap limit, and it went to 450.

THE WITNESS: Correct.

THE COURT: And I understand that that is a regulation on producers. And what I'm trying to get a clear -- from your perspective, as the operator, if you were to say, "I need this cap limit in order for me to operate this program. The reason I need this cap limit is," what?

THE WITNESS: So I think it's protection. It's the control part. So one of the things that we've seen -- and I'm not opposed to going from 150 to 450. My perspective is that we were one of the first states to implement a Medical Cannabis Program, so there wasn't a lot of information out there. And that's my opinion, so. So I think there's been a lot of development of the program, or of programs in general. And so I think that having the plant count, from a regulatory standpoint, is important so that we can say -- if I get a law enforcement call, for instance -- and I did last year from State Police for an outdoor grow -- that I can explain to them, "Okay, Producer X is licensed for this number of plants, and Producer Y is licensed for this number of plants." We can tell them what they're licensed for. I think that's some protection for producers. I think that having the plant count is also, from a regulatory standpoint, is important for the number of production locations. I think that's absolutely important. Because if we lose, I'm going to say control, or the ability to know where producers are growing, that's going to be problematic. I also think that as you get into -- numbers are numbers. 450 is 450. If you -- if there's gray in that, it's going to be difficult. So we have a tracking system, right? So if everyone does what they're supposed to do, all plants will be -- will have a label. But is it easier for plants to be into -- I'm just going to say plants -- to, "Hey, there's 2,000 plants in here. Let's just take a couple and n and no one's going to notice." So I hope those points help.

THE COURT: Okay. In your view as the operator of the program -- try and phrase this the right way. I'll use it by analogy. So when I was growing up, my parents bought me really big jeans

and then rolled them up, and then you'd grow into them. It seems the Department of Health has, in promulgating the rule, in essence said I did this survey, and based on the amount, new distributors and new -- and additional plant count, it's our view that the patient need is -- we have exceeded what the adequate supply for those patients are going to need, and they'll grow into it, rather than what, at least in part this 2013 survey does, which is look into the particular points of patient demand. Is there any reason that you know of, as an operator, why, since 2013, there hasn't been this sort of study done to make a reasonable -- to make a determination about whether or not the plant count is at all affecting a patient's adequate supply?

THE WITNESS: So I can speak about that from my time in the program.

THE COURT: Mm-hmm.

THE WITNESS: So it has been about a year that I was named director. I didn't fully transition into the position until probably late September, early October. There have been some changes. My understanding was that in speaking with the Licensing/Compliance program manager that we were going to have some data from BioTrack. And we do. It's not necessarily the data and the format that we needed. And we've been trying to get there. It just -- it hasn't been as quickly as we hoped for, for some of the reasons that I mentioned. You know, I think there's a -- we should also be looking -- I think that from our conversations with them, and we've had several, that maybe there is a way to get what we need. It just -- it might take some time.

CONCLUSIONS OF LAW:

1. A per se plant limitation per se under NMAC 7.34.4.8 for non-profit producers is not outside the scope of authority granted to the Department of Health by the Lynn and Erin Compassionate Use Act, NMSA 1978 § 26-2B-1 et seq. However, the established 450 count plant limit is contrary to the Department's obligation to ensure an adequate supply, and thus is

contrary to law. Further any plant count, and certainly the 450 plant count, it may not be simply based on outdated and unrelated data in such a manner and means as to violate the Legislature's directive to provide an adequate supply.

2. The 450-plant limitation under NMAC 7.34.4.8's for non-profit producers is arbitrary based on the outdated data, including but not limited to reliance on the original survey. Such a limit is contrary to DOH's statutory obligation under the Act.

3. NMAC 7.34.4.8's 450-plant limitation for non-profit producers prevents and impeding the purpose of the Lynn and Erin Compassionate Use Act, NMSA 1978 § 26-2B-1 et seq., from being accomplished, as the limit is arbitrary and capricious as applied to current conditions based on outdated information.

4. DOH has a duty/obligation to ensure patients enrolled in the Medical Cannabis Program can access an adequate supply of medical cannabis in New Mexico.

5. Achieving the purpose of the Lynn and Erin Compassionate Use Act, NMSA 1978 § 26-2B-1 et seq. does not require eliminating the plant count limitation altogether.

6. The phrase 'regulated system does grant authority to DOH to limit the number of plants a licensed producer may cultivate in production.

7. However, given conclusions of law in #6 above, the inclusion of the adjective "regulated" in the statute does not bestow on DOH wide-ranging power to issue whatever regulations it wants. Similarly, references in other statutes to "safety" or "welfare" do not operate as broad grants of authority; rather, the inclusion of such phrases and words are understood as general statements of purpose, not as delegations of power. "The purposes of the enabling acts, which include the goal of protecting the 'public health, safety and welfare,' are designed to invoke the general police power of the state...This general expression of legislative police

power, without more, does not create a standard for protecting ‘public health, safety and welfare.’” *In re Application of Rhino Environmental Services*, 2000-NMSC-024, ¶ 29, 117 P.3d 939. “Thus, the Court of Appeals [in the intermediate appeal] was correct to reject CDC’s reliance on the purposes of the acts as a statutory mandate to respond to issues that fit ever so loosely under the umbrella of ‘sociological concerns.’ Such a broad mandate would offer no guidance to the Department, and violate the well-settled principle that a legislative body may not vest unbridled or arbitrary power in an administrative agency.” *Id.*

8. The statute provides for “beneficial use,” and if patients cannot obtain cannabis from regulated sources in an amount which is actually beneficial, then the statute is an illusion. The specific mention of “beneficial use” in the statute signals the statute intends to build a system where cannabis is not just available in a theoretical sense—as in, each patient gets access to one gram per month at \$100 per gram—but is available in an amount which can benefit patients.

9. The relevant statute here is the Lynn and Erin Compassionate Use Act, NMSA § 26-2B-1 et seq. NMSA § 26-2B-4 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". NMSA § 26-2B-3 defines "adequate supply" as "an amount of cannabis...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."

10. Thus, the statute specifically indicates that patients may only lawfully possess an "adequate supply" and specifically directs DOH to figure out what that "adequate supply" is.

11. NMSA § 26-2B-3 does not define an "adequate supply" applicable to producers. And NMSA § 26-2B-7 does not direct the Department to promulgate any regulations regarding how much producers can produce. In fact, NMSA § 26-2B-7 instructs DOH to formulate regulations on only a few specific topics: "No later than October 1, 2007, and after consultation with the advisory board, the department shall promulgate rules in accordance with the State Rules Act to implement the purpose of the Lynn and Erin Compassionate Use Act. The rules shall: (1) govern the manner in which the department will consider applications for registry identification cards," "(2) define the amount of cannabis that is necessary to constitute an adequate supply, including amounts for topical treatments;" 3) identify criteria and set forth procedures for including additional medical conditions...;" 4) set forth additional medical conditions, medical treatments or diseases to the list of debilitating medical conditions that qualify for the medical use of cannabis as recommended by the advisory board;" 5) identify requirements for the licensure of producers and cannabis production facilities and set forth procedures to obtain licenses;" "(6) develop a distribution system for medical cannabis that provides for: (a) cannabis production facilities within New Mexico housed on secured grounds and operated by licensed producers; and (b) distribution of medical 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;" "(7) determine additional duties and responsibilities of the advisory board;" and "(8) be revised and updated as necessary."

12. The Department of Health has remained static in its production supply limit when it is delegated to adjust to the changing circumstances of its medical product. In *Rutherford v. Chaves County*, 2002-NMCA-059, ¶ 17, the Court of Appeals stated, "our case law has not

limited the concept of maintenance to ‘fixed remedies’ for static dangerous conditions...For example, the location of the school bus stop in *Gallegos* and the placement of elk warning signs in *Ryan* were remedies that may need to be changed as governmental entities learn or should learn about changes in the needs of school children or in the movement of elk.” *Id.* at ¶ 20.

13. The Court declares that the 450 plant limitation is not within the power of the Department and since it frustrates the purpose of the statute, alters the reach of the statute, and contradicts the statute, the remedy is to strike the 450 figure and remand to the Department for further proceedings to find a number which can ensure patient needs are met. The Court declares that any quantity limitation against producers which is expressed as a fixed number of plants of 450 is not within the power of the Department since it frustrates the purpose of the statute, alters the reach of the statute, and contradicts the statute, the remedy would be to strike the 450 figure and remand to the Department for further proceedings to construct a quantity limitation which ensures producers can respond to patient demand.

14. “The court ‘will not read into a statute or ordinance language which is not there.’” *Public Service Co. of New Mexico v. New Mexico Public Utility Com’n*, 1999-NMSC-040, ¶ 18. It is the *Legislature’s* role to decide if the regulation should be “strict” or not, and the *Legislature’s* silence on any production limit (in contrast to the explicit possession limit for patients), plus its seven specific enumerated items in § 26-2B-7, suggests the *Legislature* wanted a flexible, relatively hands-off, patient-centric regulatory system.

15. The Agency limit of 450 plants is arbitrary and capricious “[A]n agency rule would be arbitrary or capricious if the agency ... failed to consider an important aspect of the problem.” *Rio Grande Chapter of Sierra Club v. New Mexico Mining Com’n*, 2003-NMSC-005, ¶ 12 (internal citation omitted) (ellipsis in original).

16. The remedy for an arbitrary regulation is to remand the issue to the agency. *See New Mexico Exchange Carrier Group v. New Mexico Public Regulation Commission*, 2016-NMSC-015,32, 369 P.3d 1058 (PRC rule held arbitrary and not supported by substantial evidence was "remand[ed] this matter to the PRC for further proceedings. The record must have substantial evidence to support a finding that the newly adopted funding formula is adequate to satisfy the requirements of Section 63-9H-6(C) and (K) and Rule 17.11.10.19(C), and that the surcharge cap has not been arbitrarily established"); and *Attorney General v. New Mexico Public Regulation Commission*, 2011-NMSC-034,18-19, 150 N.M. 174, 258 P.3d 453 ("The PRC's adoption of the adder rates was arbitrary and unlawful in that they were not evidence-based, cost-based, nor utility specific. We conclude, therefore, that the PRC's Final Order is inconsistent with the law because the PRC had no basis in the record for determining that the adder rates contained in Alternative A were 'just and reasonable.' We therefore annul and vacate the PRC's Final Order due to the lack of a lawful basis in the record to support its decision. We remand this case to the PRC for further proceedings in accordance with this Opinion").

17. The Department of Health exceeded their statutory authority by, without justification, altering, modifying and limiting the reach of the Act created by the Legislature by their unsupported limit of 450 plants per producer.

18. DOH's altering of the Act is not permitted. The New Mexico Supreme Court has stated,

A governor's proper role is the execution of the laws. NM Const. Art. V, § 4. Public assistance programs must be administered, and we recognize that such administration involves discretion by executive agencies. Yet, such discretion is not boundless. Generally, the Legislature, not the administrative agency, declares the policy and establishes primary standards to which the agency must

conform. *See State ex rel. State Park & Recreation Comm'n v. New Mexico State Authority*, 76 N.M. 1, 13, 411 P.2d 984, 993 (1966).

The administrative agency's discretion may not justify altering, modifying or extending the reach of a law created by the Legislature. *See, e.g., Chalamidas v. Environmental Improvement Div. (In re Proposed Revocation of Food and Drink Purveyor's Permit)*, 102 N.M. 63, 66, 691 P.2d 64, 67 (Ct.App.1984) (stating that an "agency cannot amend or enlarge its authority through rules and regulations"); *Rainbo Baking Co. v. Commissioner of Revenue*, 84 N.M. 303, 306, 502 P.2d 406, 409 (Ct.App.1972).

While recognizing the specific roles of each branch of government, we also note that absolute separation of powers is "neither desirable nor realistic," *State ex rel. Clark*, 1995–NMSC–051, 120 N.M. at 573, 904 P.2d at 22, and that the constitutional doctrine of separation of powers permits some overlap of governmental functions, *Mowrer v. Rusk*, 95 N.M. 48, 53, 618 P.2d 886, 891 (1980). Nonetheless, this Court must give effect to Article III, Section 1, and will not be reluctant to intervene where one branch of government unduly encroaches or interferes with the authority of another branch. *State ex rel. Clark*, 1995–NMSC–051, 120 N.M. at 573, 904 P.2d at 22; *Rusk*, 95 N.M. at 54, 618 P.2d at 892. Such an infringement occurs when the action by one branch prevents another branch from accomplishing its constitutionally assigned functions. *State ex rel. Clark*, 1995–NMSC–051, 120 N.M. at 574, 904 P.2d at 23 (citing *Nixon v. Administrator of Gen. Servs.*, 433 U.S. 425, 433, 97 S.Ct. 2777, 53 L.Ed.2d 867 (1977)).

"The test is whether the Governor's action disrupts the proper balance between the executive and legislative branches." *State ex rel. Clark*, 1995–NMSC–051, 120 N.M. at 574, 904 P.2d at 23. If a governor's actions infringe upon "the essence of legislative authority—the making of laws—then the [g]overnor has exceeded his authority." *State ex rel. Clark*, 1995–NMSC–051, 120 N.M. at 573, 904 P.2d at 22.

A violation occurs when the Executive, rather than the Legislature, determines "how, when, and for what purpose the public funds shall be applied in carrying on the government," *State ex rel. Schwartz v. Johnson*, 1995–NMSC–083, ¶ 14, 120 N.M. 820, 907 P.2d 1001 (quoting *State ex rel. Holmes v. State Bd. of Fin.*, 69 N.M. 430, 441, 367 P.2d 925, 933 (1961)). In addition, infringement upon legislative power may also occur where the executive does not "execute existing New Mexico statutory or case law [and rather attempts] to create new law." *State ex rel. Clark*, 1995–NMSC–051, 120 N.M. at 573, 904 P.2d at 22.

State ex rel. Taylor v. Johnson, 1998–NMSC–015, ¶¶ 22–24, 125 N.M. 343, 349–50, 961 P.2d 768, 774–75

19. While it may be true that DOH was delegated the authority to regulate the system of distribution of medical marijuana in this State, it may not create its own arbitrary production number that does not have reasonable nexus in law or fact to adequate supply for patients in the program.

“An administrative agency has no power to create a rule or regulation that is not in harmony with its statutory authority.” *Rivas v. Bd. of Cosmetologists*, 101 N.M. 592, 593, 686 P.2d 934, 935 (1984). The Legislature may delegate legislative duties to a board, “but in so doing, boundaries of authority must be defined and followed.” *Id.*

Wilcox v. New Mexico Bd. of Acupuncture & Oriental Med., 2012-NMCA-106, ¶ 7, 288 P.3d 902, 905

20. DOH’s reliance on the fear of Federal government intervention in the State run program may not be the sole basis for its plant count limit.

21. The DOH in implementing this goal may not simply ignore the statutory requirement of ensuring an adequate supply for the growing and diverse needs of the patients. As such, DOH’s actions fail as a matter of law and they are not reserved simply for administrative discretion.

22. While the Court is reluctant to intervene in such a dispute, the issue of whether an agency has exceeded its statutory mandate by the legislature is one that must be decided by the Court’s original jurisdiction.

It is axiomatic that an administrative agency’s power to promulgate regulations may extend only as far as its legislative grant of authority. *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208, 109 S.Ct. 468, 102 L.Ed.2d 493 (1988); see *In re Vt. Gas Sys., Inc.*, 150 Vt. 34, 39, 549 A.2d 627, 630 (1988) (“An administrative agency’s rule-making authority cannot support an expansive interpretation of its own powers.”).

Thus, while we generally presume the validity of regulations within the agency’s authority, we will uphold an administratively adopted regulation only “where we can do so without compromising the intent of the statute which authorized it.” *In re Agency of Admin.*, 141 Vt. 68, 74, 444 A.2d 1349, 1351–52 (1982); see *Vt.*

Ass'n of Realtors, Inc. v. State, 156 Vt. 525, 530, 593 A.2d 462, 465 (1991) (“[W]e will not countenance any agency rule that exceeds the authority delegated to the agency under its enabling act.”). If an agency operates outside the bounds, or for purposes other than those, authorized by the enabling legislation, “this Court will intervene.” *In re Agency of Admin.*, 141 Vt. at 75, 444 A.2d at 1352.

Martin v. State, Agency of Transp. Dept. of Motor Vehicles, 2003 VT 14, ¶ 15, 175 Vt. 80, 87, 819 A.2d 742, 749 (2003)

and

The fundamental principle served by these tenets is the doctrine of separation of powers. See 1A N. Singer, *Statutes and Statutory Construction* § 31.06, at 544 (5th ed.1993). Courts have generally upheld broad delegations of authority to administrative agencies, but agency action that “transcends the delegation will not be sustained.” 1 J. Stein, G. Mitchell & B. Mezines, *Administrative Law* § 3.03[5], at 3–110 (2002). Confining delegated lawmaking authority within its intended bounds helps to assure that ultimate control over policymaking rests with the legislative branch of government rather than unelected administrative officials. 1 N. Singer, *Statutes and Statutory Construction* § 4.15, at 166 (5th ed.1994); see *Chambers v. St. Mary's Sch.*, 82 Ohio St.3d 563, 697 N.E.2d 198, 202 (1998) (legislative accountability is cornerstone of democratic process that justifies general assembly's role as lawmaker and restricts administrative rule-making to placing general assembly's policy into effect).

Martin v. State, Agency of Transp. Dept. of Motor Vehicles, 2003 VT 14, ¶ 16, 175 Vt. 80, 87, 819 A.2d 742, 749–50 (2003)

23. Finally, the Court has the greatest sympathy for the Department of Health and its Cabinet Secretary in implementing a program that is new and evolving and uniquely a program that might run afoul of federal criminal statutes that govern the subject matter. That said, New Mexico Courts have not accepted an “Administrative Necessity” defense to an Agency’s regulatory overreach because what they are tasked to do is difficult.

Finally, the State argues that the challenged regulation is a valid exercise of DMV's authority because it is administratively necessary. Again, we find this argument unpersuasive. Agencies generally may not choose to ignore “their statutory mandate because they believe it is administratively inefficient or infeasible.” *Campbell v. United States Dep't of Agric.*, 515 F.Supp. 1239, 1249 (D.D.C.1981) (agency cannot decide not to allow food stamp recertifications at Social Security offices because of practical problems they perceive in doing so). 1314 ¶ 29. In very limited circumstances, “administrative necessity may be a basis for finding implied authority for an administrative approach not explicitly

provided in the statute.” *Ala. Power Co. v. Costle*, 636 F.2d 323, 358 (D.C.Cir.1979). A court may uphold streamlined agency approaches or procedures involving categorical exemptions not explicitly provided by statute when a case-by-case approach would, as a practical matter, prevent the agency from carrying out its legislatively authorized mission. *Id.* But the agency’s burden to justify its actions “in such a case is especially heavy.” *Id.* at 359.

¶ 30. The State has not met that heavy burden here. Cf. *Pub. Citizen, Inc. v. Shalala*, 932 F.Supp. 13, 17 (D.D.C.1996) (FDA failed to demonstrate administrative impossibility of applying statute’s nutrition content and health claim provisions to restaurant menus). There is no evidence that DMV could not carry out its statutory mandate without imposing overbroad categorical exclusions that sever the statutory nexus between the denial and the offensiveness of the requested plate.

¶ 31. In support of its administrative necessity argument, the State states simply that the Commissioner would be unable to handle the growing number of special plate applications without regulatory standards to implement the program. We do not suggest otherwise. DMV may promulgate regulations consistent with the statute, and, in doing so, may establish lists of combinations of numbers and letters that might be offensive. DMV may also, consistent with § 304(d), exclude entire categories comprised exclusively of words that might offend the general public. Cf. *McMahon v. Iowa Dep’t of Transp.*, 522 N.W.2d 51, 55–57 (Iowa 1994) (upholding regulation disallowing combinations of numbers and letters that have sexual connotations or that are defined in dictionaries as terms of vulgarity, contempt, prejudice, hostility, insult, or racial or ethnic degradation); *Higgins v. DMV*, 170 Or.App. 542, 13 P.3d 531, 533 n. 3–4 (2000) (en banc) (construing regulation defining “ethnic words” as words that refer to definable class of persons, and that ridicule or support superiority of that class). The agency may not, however, claim the authority to establish policy unauthorized by statute solely because the task is fraught with difficulty. If the Legislature has set DMV “with an impossible task, their remedy is with [the Legislature] and not this Court.” *Campbell*, 515 F.Supp. at 1249.

Martin v. State, Agency of Transp. Dept. of Motor Vehicles, 2003 VT 14, ¶¶ 28-31, 175 Vt. 80, 91–92, 819 A.2d 742, 752–53 (2003)

24. The language of the Statute must prevail over the agency regulation, and the DOH may not overrule the portion of the Act that provides for adequate supply by such a restrictive and unsupported plant count regulation.

If there is a conflict or inconsistency between statutes and regulations promulgated by an agency, the language of the statutes shall prevail. An agency by regulation cannot overrule a specific statute.

Jones v. Employment Services Div. of Human Services Dept., 1980-NMSC-120, ¶ 3, 95 N.M. 97, 99, 619 P.2d 542, 544

IT IS THEREFORE ORDERED:

DOH is enjoined from enforcing the 450 quantity limitation against producers described in its rule. The injunction is stayed for 120 days to provide DOH an opportunity to amend NMAC 7.34.48 to comply with the §26-2B-1 et. seq. and NMAC 7.34.4.7B.

The Court enters judgment in favor of Plaintiffs, against Defendants, and invalidates NMAC 7.34.4.8(A)(2), consistent with this ruling.

The Court DENIES Plaintiff request to declare that DOH has no authority to regulate the medical cannabis industry by means of a plant count as long as such count is based in fact and does not impede the purpose of the act.

Any Finding of Fact or Conclusion of Law not incorporated are rejected. The prevailing party shall prepare a form of Order.



HONORABLE DAVID K. THOMSON
District Court Judge, Division VI

CERTIFICATE OF MAILING

I hereby certify that a true copy of the foregoing Order was served electronically to the following parties/counsel of record at the following addresses this date of filing.

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Summary

Although a recent survey of all 34 commercial producers suggests that a maximum of 3,100 mature plants per producer is sufficient to meet New Mexico's *current* demand for medical cannabis, recent statutory and regulatory changes are expected to increase potential demand by an estimated 21.1 million grams annually. These changes, combined with anticipated growth in program enrollment, will increase the necessary plant count to 5,000 mature plants per producer by 2022.

With the enactment of the Erin and Lynn Compassionate Use Act the Legislature intended to ensure patients access to medical cannabis from legal sources; but ensuring access requires more than simply decriminalizing production and possession for licensees and cardholders. Medical cannabis is not accessible if it is not affordable and licensed producers cannot crowd-out illicit sellers if they cannot compete effectively on price. By keeping prices in the regulated market well above competitive levels, restrictive commercial producer grow limits subvert legislative intent by depriving patients of access and fueling growth of the illicit market.

Data from regulated markets in other states show per capita consumption climbing as markets grow and mature. In contrast, data from the DOH indicates a downward trend in consumption per qualified patient. Declining purchases from regulated suppliers point to increasing reliance on the illicit market by qualified patients.

Because they are largely unregulated, personal production licensees (PPLs) constitute a far greater diversion risk than commercial producers. By further loosening the already lax regulatory constraints on personal production, provisions of SB 406 exacerbate the risk of diversion and increase the disparity in access between qualified patients who hold PPLs and patients who obtain their cannabis solely from commercial producers. Under the provisions of SB 406, a single PPL could produce upwards of 20 pounds of useable cannabis each year. Commercial producers, in contrast, are permitted to produce a combined maximum of roughly 1.1 pounds per patient per year (an average of .03 pounds per patient per commercial producer) under the 450 plant limit and 6.2 pounds per patient per year (an average of .18 pounds per patient per commercial producer) under the 2,500 plant limit.

If commercial producers and the qualified patients they serve were subject to the same cultivation constraints as personal production licensees, the maximum plant count would be 10,000 per commercial producer.

In light of these considerations, we encourage the Department to adopt medical cannabis production limits consistent with the following best practices, each of which is described in more detail in the body of this memo.

- 1. Grow limits should apply to mature plants only**
- 2. Grow limits should not constitute binding production constraints on responsible growers.**
Capping cultivation does little to prevent diversion and artificially inflates the price patients must pay, driving patients to the illicit market and allowing inefficient producers to remain profitable.
- 3. Grow limits should be part of a tiered licensure structure that imposes higher licensure fees on larger producers and allows for stacking of top tier licenses.**
- 4. Grow limits should be based on plant count rather than canopy**
Neither canopy nor plant count is particularly effective for ensuring that commercial producers produce no more or less than is necessary to meet patient demand. That said, plant count is the method to which commercial producers are accustomed and the majority of medical cannabis producers (53%) surveyed preferred plant count.

5. **Grow limits should equalize access for PPL holders and patients who buy exclusively through dispensaries.**
 Plant count limits should enable commercial producers to produce at least the same amount of cannabis per qualified patient as PPL holders are permitted to produce for themselves.
6. **Grow limits should be based on patient need and should therefore be a function of the number of qualified patients.**
 Maximum plant counts should be indexed to program enrollment

I. Demand

Recent statutory and regulatory changes along with anticipated growth in MCP enrollment are expected to significantly increase medical cannabis demand in New Mexico. SB 406, signed into law by Governor Lujan-Grisham in April 2019, and the anticipated addition of opioid use disorder to the list of MCP qualifying conditions will add *the equivalent of 22,913* qualifying patients to the MCP, increasing potential demand for medical cannabis by approximately 21.1 million grams annually.

Demand for medical cannabis already greatly exceeds supply. Table I shows the estimation of demand and surplus demand (demand in excess of supply) under current law and after full implementation of SB 406 and the addition of opioid use disorder as a qualifying condition. Total demand, assuming 70,600 qualified patients, each entitled to an “adequate supply” of 920 grams of medical cannabis annually, is 65 million grams (143,195 lbs) under current law and 86 million grams (189,668 lbs) after full implementation of recent and anticipated statutory and regulatory changes. Surplus demand, which is total demand minus production by PPLs and commercial producers, is 48 million grams currently and 67.5 million grams after statutory and regulatory changes are fully enacted.

Table I Demand Estimation		
	Current	New Laws
Patients (12/18)	70,600	93,513
Grams/Year/Patient (Max)	920	920
Total Demand (G)	64,952,000	86,031,960
- PPL Production (G)	(5,287,093)	(7,003,002)
commercial producer Demand (G)	59,664,907	79,028,958
- commercial producer Production (12/18)	-11,516,132	-11,516,132
Surplus commercial producer Demand (G)	48,148,775	67,512,826

Assuming an average of four harvests per year and that each plant harvested yields 20 ounces of useable cannabis, implementation of the new laws will increase the number of plants necessary to meet current demand from 114,556 to 151,735.

Why current purchases are a poor measure of patient demand

State statute requires that the MCP ensure that qualified patients have uninterrupted access to a supply of legally produced medication adequate to meet their individual healthcare needs. Access is a function of numerous factors, not least among them price. Price is determined, in large part, by supply. When demand exceeds supply, prices rise.

In a period during which prices have fallen, sometimes quite dramatically, in many medical cannabis states, cannabis prices in New Mexico have actually risen. Advocates for restrictive grow limits point to the fact that many MCP patients do not purchase the full 230 gram 90-day maximum as evidence that demand is being met by current supply; but this assessment ignores the reality that, at over \$10/gram a three month “adequate” supply of medical cannabis costs \$2,300, or almost \$10,000 annually, far more than most New Mexicans, particularly those who are sick and/or disabled can possibly afford.

Ruling in *Sena v. Gallagher*, Judge David K. Thompson affirmed the existence of “pent-up” demand from patients who are not enrolled in the program precisely because they do not have access to medicine,” further noting that, because it is not evident in the legal marketplace, “this demand is essentially silent.”

A recent survey of commercial producers suggests that a maximum plant count of 3,100 per commercial producer would be sufficient to meet New Mexico's current demand for medical cannabis. However, recent policy changes and 47 percent annual growth in program enrollment are expected to increase that number to at least 5,000 mature plants by 2022.

A. Policy Changes Expected to Impact Demand

This section describes in more detail recent and anticipated statutory and regulatory changes that are likely to impact medical cannabis demand.

SB 406, Effective June 14, 2019

SB 406 makes a number of changes to the MCP that improve patient access and further normalize the medical use of cannabis, including:

- Removing barriers to access by allowing 3-year recertification and telehealth evaluations
- Increasing access to the MCP by residents of other states
- Making higher potency products available to patients
- Allowing use of medical cannabis in schools and by patients under state supervision

Several provisions of the new law, most notably those that increase access to the New Mexico MCP by residents of other states, are expected to increase medical cannabis demand by 19.7 million grams annually.

a) Residents of Other States

(1) Reciprocity

Reciprocity will allow patients registered with medical cannabis programs in other jurisdictions to participate in New Mexico's MCP. The law defines "reciprocal participant" as "an individual who holds proof of authorization to participate in the medical cannabis program of another state of the United States, the District of Columbia, a territory or commonwealth of the United States or a New Mexico Indian nation, tribe or pueblo." Unlike some of the 20 other medical cannabis reciprocity states, New Mexico does not require reciprocity applicants to have a New Mexico qualifying condition.

Each year, New Mexico receives over 9 million overnight visits from residents of other states with medical cannabis programs. If just one half of one percent (.05%) of these visitors request reciprocity, New Mexico's medical cannabis customer base will increase by almost 47,000 patients.¹ If each reciprocity patient purchases one ounce, annual demand will increase by an addition 1.3 million grams.

Medical cannabis authorizations issued by tribal governments are another potential source of reciprocity applicants.

(2) State Residency Requirements for MCP Participation

¹ Hawaii established reciprocity in 2018. Unlike New Mexico, Hawaii requires reciprocity applicants to have one of the state's 14 qualifying conditions. Hawaii, which receives about 6 million visitors from the U.S. mainland annually, anticipates 5,000 mature plants reciprocity applications in the first year. See <https://mjbizdaily.com/severe-pain-common-mmj-ailment-hawaii>

The new definition of qualified patient as “a person who has been diagnosed by a practitioner as having a debilitating medical condition and has received written certification and a registry identification card pursuant to the Lynn and Erin Compassionate Use Act”² eliminates the requirement that MCP applicants be New Mexico residents and could thereby open the door to residents of other states becoming MCP cardholders. Other provisions of the new legislation, including three-year cards and telehealth certifications, will further facilitate access to New Mexico’s MCP by out-of-state patients.

Four of New Mexico’s five border states have their own medical cannabis programs. The exception, Texas, is home to over 26 million people, roughly two million of whom live within 2 hours of the New Mexico border.³ If one percent of Texans living in close proximity to the New Mexico border enroll in the MCP, the program will add 20,000 patients and demand will increase by 18.4 million grams annually.⁴

b) Authorization and Access

SB 406 increases access for qualifying patients by decreasing the frequency with which patients must recertify and allowing for evaluation via telehealth. Three-year recertification will help to ensure continuous enrollment with less attrition. Telemedicine certification⁵ will also increase ease of access and, in conjunction with changes to residency requirements, will facilitate access to the MCP by patients who reside outside New Mexico.

c) Normalization

SB 406 further normalizes the medical use of cannabis in New Mexico by affirming that “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 supervision of a physician.”

Other provisions of the law, including permitting the use of medical cannabis in schools, providing protections for medical cannabis use at work and by individuals under state supervision, and amendments to the Anatomical Gift Act and the Family Services Act all affirm state support for medical cannabis use by qualified patients. The impact of these provisions on medical cannabis demand is hard to predict for a variety of reasons including differing interpretations of the state supervision language and school district discretion in allowing medical cannabis use by students. It seems reasonable to expect that evidence of greater acceptance of medical cannabis by the state will ultimately encourage more patients to obtain cannabis cards and thereby increase demand.

d) Potency

SB 406 prohibits the DOH from regulating the THC concentration in cannabis products. Under prior DOH rule, commercial producers were prohibited from selling concentrated cannabis products over 70 percent THC unless the purchaser had a medical exception from the DOH. Production of higher THC products will require more plant material, but the impact this provision will have on demand is highly uncertain and not expected to be large.

² Section 26-2B-3 (v) NMSA 1978

³ Technically, Texas has a medical cannabis program, but it is extremely limited. The state’s Compassionate Use Act, implemented in early 2016 and run by the Texas Department of Public Safety, allows patients with intractable epilepsy and a doctor’s recommendation to obtain low-THC cannabis oil. No other cannabis products or conditions are permitted

⁴ The average penetration rate across all medical cannabis states is about 1.1%. As of March 2019, roughly 3.3% of New Mexico’s population participated in the MCP.

⁵ Telehealth is permitted after an initial in-person visit

Opioid Use Disorder

The Medical Cannabis Advisory Board approved the addition of opioid use disorder as an MCP-qualifying condition on March 29, 2019. DOH Secretary Kunkel is expected to accept the Board's recommendation.⁶

Precise estimates of the prevalence of opioid use disorder in New Mexico are hard to come by. The 2016-2017 National Survey on Drug Use and Health estimated that 9,000 New Mexicans ages 12 and older experience "pain-reliever use disorder" and another 55,000 mature plants experience "illicit drug use disorder."⁷ ⁸ A recent Milliman study estimated that in 2015 about 15,000 insured New Mexicans actively experienced diagnosed opioid abuse, dependence, or poisoning.⁹ The actual number of New Mexicans who could qualify for the MCP on the basis of opioid use disorder is likely much higher because not all New Mexicans have health insurance and not all cases of opioid use disorder are diagnosed. On the other hand, some of the patients who would qualify for the MCP due to opioid misuse may already be enrolled in the MCP due to chronic pain or other qualifying conditions. These contravening factors make it difficult to predict the impact of adding opioid use disorder to the list of qualifying conditions. Nonetheless, the impact is likely to be significant: If ten percent of insured New Mexicans with diagnosed opioid use disorder enrolled, the MCP would add 1,500 new qualifying patients and demand would increase by 1.4 million grams annually.¹⁰

II. Evidence of a Thriving Illicit Market

States establish medical cannabis programs to help ensure that qualified patients can access the medicine they need without turning to illicit sellers; but ensuring access requires more than simply decriminalizing production and possession for licensees and cardholders. Medical cannabis is not accessible if it is not affordable and licensed producers cannot crowd-out illicit sellers if they cannot compete effectively on price. By keeping prices in the regulated market well above competitive levels, restrictive commercial producer grow limits fuel growth of the illicit market.

MCP policies contribute to both demand and supply in the illicit cannabis market. While overly stringent grow limits keep dispensary prices too high for many patients, lax regulation of PPLs fosters the flow of New Mexico homegrown into illicit supply channels. Qualified patients priced out of the legal market are turning to illicit sellers, some of whom hold PPLs, to obtain their medicine.

This contention is supported by rich anecdotal evidence and by data published in DOH patient and producer reports. These data illustrate trends not evident in state cannabis markets where regulated production by properly licensed producers has been allowed to fluctuate in response to patient demand.

As of March 2019, just over 7,500 qualified patients held personal production licenses. The percentage of PPLs who are actively growing cannabis appears to have risen in recent years. Half of PPL holders surveyed in 2013 and three-quarters of those surveyed in 2019 said they were using their PPL to grow cannabis.

⁶ "Medical Cannabis Advisory Board Approves Petition to Add Opioid Use Disorder as Qualifying Condition for the Medical Cannabis Program." <https://nmhealth.org/news/information/2019/3/?view=752>

⁷ "Illicit Drug Use" includes the misuse of prescription psychotherapeutics or the use of cannabis, cocaine (including crack), heroin, hallucinogens, inhalants, or methamphetamine

⁸ <https://www.samhsa.gov/data/report/2016-2017-nsduh-state-specific-tables>

⁹ http://www.milliman.com/uploadedFiles/insight/2018/Opioid_Use_Disorder_Prevalence.pdf

¹⁰ Three states – Pennsylvania, New York, and New Jersey - currently include opioid use disorder as a qualifying condition for their medical cannabis programs. These provisions have not been in effect long enough to discern their effects on program enrollment.

While regulated cannabis prices in other states such as Colorado, Oregon, Washington, and Arizona have declined, sometimes quite dramatically, as programs have grown,¹¹ New Mexico cannabis prices have actually increased from an average of \$9.56/gram in the first quarter of 2018 to \$10.16/gram in the fourth quarter.¹²

Data from the DOH indicates a downward trend in consumption per qualified patient. Declining purchases from regulated suppliers point to increasing reliance on the illicit market by qualified patients.

While producers in other states grapple with mounting surpluses, New Mexico commercial producer inventories are declining. Commercial producers reported 1.1 million grams of flower and bud in stock as of December 31, 2018, 35 percent less than the 1.7 million grams of inventory one year earlier. Because the decline in inventory coincided with a near doubling

of MCP enrollment, per capita inventory fell 57 percent, from 37 grams per patient at the end of 2017 to 16 grams per patient in December 2018.

Data from regulated markets in other states show per capita consumption climbing as markets grow and mature.^{13, 14} In contrast, data from the DOH indicates a downward trend in consumption per qualified patient. Declining purchases from regulated suppliers point to increasing reliance on the illicit market by qualified patients.

III. Adequate Supply and PPL Parity

By further loosening the lax regulatory constraints on personal production, provisions of SB 406 exacerbate the disparity in access between qualified patients who hold PPLs and patients who obtain their cannabis solely from commercial producers. SB 406 authorizes personal production licensees to be in possession of their entire harvest, even if that amount exceeds the current “adequate supply” limit of 8 ounces per 3-month period.¹⁵

Section 26-2B-4 NMSA 1978 (being Laws 2007, Chapter 210, Section 4) is amended to read:
"26-2B-4. EXEMPTION FROM CRIMINAL AND CIVIL PENALTIES FOR THE MEDICAL USE OF CANNABIS. --

A. 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*"

PPL holders are allowed to possess up to four mature cannabis plants at any one time. If each plant yields 20 ounces of useable cannabis, a single harvest could easily yield five pounds. With four harvests annually, a single PPL could produce 20 pounds of useable cannabis each year. Commercial producers, in contrast, are permitted to produce a combined maximum of roughly 1.1 pounds per patient per year (an average of .03 pounds per patient per commercial producer) under the 450 plant limit and 6.2 pounds per patient per year (an average of .18 pounds per patient per commercial producer) under the 2,500 plant limit.

¹¹ BDS Analytics' Cannabis Retail Price Index (CPI) & Cannabis Consumer Sales Report - February, 2019. Retrieved from: <https://bdsanalytics.com/wp-content/uploads/2019/04/CPI-Template-Feb19.pdf>

¹² New Mexico Department of Health Quarterly commercial producer Reports. Retrieved from: <https://nmhealth.org/about/mcp/svcs/pdb/>

¹³ Colizzi, M. and Bhattacharyya, S. (2018) Cannabis use and the development of tolerance: a systematic review of human evidence, *Neuroscience & Biobehavioral Reviews*, Volume 93 Pages 1-25, <https://doi.org/10.1016/j.neubiorev.2018.07.014>.

¹⁴ Twenty-four percent of respondents to DOH's March 2019 MCP patient survey said that tolerance had caused them to increase their consumption of cannabis over time.

¹⁵ 7.34.3.9 NMAC

If commercial producers and the qualified patients they serve were subject constraints equivalent to that of PPL holders, the maximum commercial producer plant count would be 10,000 after implementation of SB 406 and the addition of opioid use disorder to the list of MCP qualifying conditions.

IV. Production Quotas

Grow limits may be a useful basis for a system of tiered licensure, but when production limits impose binding production constraints on responsible growers they do more harm than good. Although some states like Michigan and Hawaii use plant count or canopy size as the basis for tiered licensure fees, most medical cannabis states do not place an absolute cap on production.

There are strong economic rationales for not placing quotas on medical cannabis production, especially when licenses are capped. Limits on plant count or canopy size may give the impression that the state is preventing over-supply, but, in reality, capping cultivation does little to prevent diversion and artificially inflates price patients must pay, driving patients to the illicit markets and allowing inefficient producers to remain profitable.

Making growing area or plant count a binding constraint on production encourages producers to make adaptations to maximize yield per square foot. These adaptations can drive up production costs and push producers to cultivate only the highest yielding strains resulting in less variety for consumers.¹⁶

Production limits attempt to minimize diversion by ensuring that legal production does not exceed the amount that can be sold in legal markets. Although this logic may work for more conventional pharmaceuticals, grow limits are not effective compliance mechanisms for cannabis because neither canopy size nor plant count are reliable predictors of statewide yield. Numerous factors including type of grow, number of harvests, height of canopy, strains cultivated, and random factors such as crop failure impact yield. A 1,000 square foot outdoor canopy could yield 80 pounds of useable cannabis annually while an otherwise identical indoor grow with 5 harvests per year could easily yield 400 pounds per year.

In large, vigorous, and appropriately regulated legal markets intense competition results in lower prices. As has been the case in other states, allowing commercial producers to produce enough cannabis to meet patient demand will likely result in lower prices. Falling prices will narrow profit margins for some producers, forcing them to become more efficient or exit the market. The role of regulation is not to protect inefficient producers from the rigors of a competitive marketplace.

Finally, stifling production by licensed producers does not prevent cannabis market concentration, rather it shifts that concentration and attendant market power into the illicit market. New Mexico could more effectively combat excessive market concentration by reducing the significant barriers to entry created by high up-front licensure fees.

Production Limit Recommendations

If production limits are implemented, adherence to the following six guidelines is recommended:

- I. Grow limits should apply to mature plants only**

¹⁶ How to Regulate Cannabis A Practical Guide. Transform Drug Policy Foundation May 2014.
<https://www.unodc.org/documents/ungass2016/Contributions/Civil/Transform-Drug-Policy-Foundation/How-to-Regulate-Cannabis-Guide.pdf>

2. **Grow limits should not constitute binding production constraints on responsible growers.**
3. **Grow limits should be part of a tiered licensure structure that imposes higher licensure fees on larger producers and allows for stacking of top tier licenses.**

The production tiers presented in Table 2 are similar to those implemented in Michigan. Licensure fees increase with plant count. Tier 3 licensees who wish to operate larger grows can purchase and stack multiple tier 3 licenses, each of which authorize the grower to grow up to 3,000 cannabis plants in a single location. The licensure tiers proposed in Table 2 also align with the production strata evident in producer responses to the question about optimal plant count posed on the 2019 survey.

Tier	Maximum Mature Plants	Annual Fee	Stackable?
1	500	\$5,000	No
2	1,500	\$15,000	No
3	3,000	\$30,000	Yes

4. **Grow limits should be based on plant count rather than canopy**
As noted earlier, neither method is particularly effective for ensuring that commercial producers produce no more or less than is necessary to meet patient demand. That said, plant count is the method to which commercial producers are accustomed and the majority of medical cannabis producers (53%) surveyed preferred plant count.
5. **Grow limits should equalize access for PPL holders and patients who buy exclusively through dispensaries.**
Plant count limits should enable commercial producers to produce at least the same amount of cannabis per qualified patient as PPL holders are permitted to produce for themselves
6. **Grow limits should be based on patient need and therefore be a function of the number of qualified patients.**
Maximum plant counts should be reassessed bi-annually and indexed to program enrollment

My Commission Expires: 2/25/22

AFFIDAVIT OF DAVID MUSCARELLA

STATE OF NEW MEXICO)
) ss:
COUNTY OF Bernalillo)

David Muscarella, being duly sworn, states as follows:

1. My name is David Muscarella and I work for Urban Wellness
2. My position at Urban Wellness is Chief Executive Officer.
3. I have worked in the cannabis field for over 4 years.
4. I am familiar with the cultivation practices of Urban Wellness.
5. Urban Wellness substantially cultivates cannabis from clones, not seeds.
6. A clone is a cutting we take from a mature, non-flowering plant.
7. The clone cutting is usually four to six inches high.
8. We place the cutting into a grow block and feed with water and nutrients, and from there it grows into a mature plant.
9. We use clones rather than seeds to maintain the consistency of our products offered.

FURTHER AFFIANT SAYETH NAUGHT.

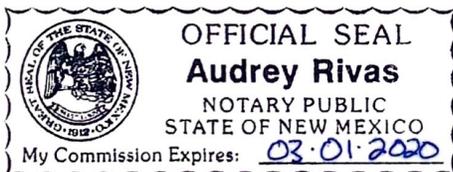

(witness' signature)

STATE OF NEW MEXICO)
) ss:
COUNTY OF Bernalillo)

The Affiant David Muscarella subscribed and swore to his affidavit in my presence on July 10, 2019


Notary Public

My Commission Expires: 03-01-2020





Ultra Health[®]

March 25, 2019

VIA Mail and Email

Kathyleen M. Kunkel

Kenny Vigil

New Mexico Department of Health

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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 15 ounces. ~~230 total units~~. For purposes of department rules, this quantity is deemed an adequate supply. ~~(For ease of reference: 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.

B. Dry weight measurement: Calculation of units: For purposes of department rules, 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. ~~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 amount ~~number of units~~ 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:

<p><u>First Purchase:</u> 1 oz flower + 1500 mg concentrate + 200 mg edible = 1 oz + 1700 mg 1 oz flower + 0.053 oz concentrate + 0.007 oz edible = 1.06 oz usable cannabis</p> <p>15 oz purchase limit – 1.06 oz purchased = 13.94 oz remaining purchase limit</p>
<p><u>Second Purchase:</u> 2 oz flower + 500 mg concentrate + 1000 mg edible = 2 oz + 1500 mg 2 oz flower + 0.018 oz concentrate + 0.035 oz edible = 2.053 oz usable cannabis</p> <p>13.94 oz purchase limit – 2.053 oz purchased = 11.887 oz remaining purchase limit</p>
<p><u>Third Purchase:</u> 0.5 oz flower + 6000 mg concentrate + 60 mg edible = 0.5 oz + 6060 mg 0.5 oz flower + 0.212 oz concentrate + 0.002 oz edible = 0.714 oz usable cannabis</p> <p>11.887 oz purchase limit – 0.714 oz purchased = 11.173 oz remaining purchase limit</p>

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.

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:

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

*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

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Via U.S. Postal Mail

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.

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



[EXT] Comment on proposed new NMAC 7.34.2.7, 7.34.3.7, 7.34.4.7

Sean McAfee <smcafeelaw@gmail.com>

Thu 7/11/2019 4:18 PM

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

To: NM Department of Health

Re: Proposed amendments to NMAC 7.34.2.7, 7.34.3.7, 7.34.4.7

I represent the New Mexico Beneficial Products Manufacturers Cooperative Association, an association of manufacturers licensed under the Lynn and Erin Compassionate Use Act who provide medicinal cannabis products for use by the NM Medical Cannabis Program's patients. These manufacturers provide an invaluable service to patients who prefer to take their medicine in forms other than via inhalation of smoke from raw plant material. I write on the Association's behalf, and on behalf of all manufacturers.

With the passage of SB 406, the legislature clearly and specifically confirmed its continued intent to provide for the existence of manufacturers within the statutory scheme of the Lynn and Erin Compassionate Use Act. Because the very existence of manufacturers was the subject of a legal challenge by producer NM Top Organics, (New Mexico Top Organics-Ultra Health Inc. v. NM Dept of Health Medical Cannabis Program, D-101-CV-2018-03519), it is important the new rules appropriately and accurately reflect that intent. Further, it is important that they are sufficiently specific so as to not invite additional challenge, and withstand such challenge when and if made.

Accordingly, I suggest the following additions (in red italics) to the proposed new rules, specifically these definitions:

7.34.2.7; 7.34.3.7 and 7.34.4.7 Definitions

K. **"Cannabis-derived product"** means a product, other than cannabis itself, which contains or is derived from cannabis, not including hemp. *Cannabis which is intended to be converted into a cannabis-derived product is considered a cannabis-derived product at such time it is provided to a licensed manufacturer for the purpose of creation of a cannabis-derived product.*

(...)

Y. **"Manufacturer"** means a ~~[business entity that manufactures cannabis-derived product that has been approved for this purpose by the medical cannabis program]~~ person that is licensed by the department to manufacture cannabis products; package, transport or courier cannabis products; have cannabis products tested by a cannabis testing facility; *purchase, obtain and transport cannabis for the purpose of manufacturing cannabis-derived product*, purchase, obtain, sell and transport cannabis products to other cannabis establishments; and prepare products for personal production license holders.

[...]

While the new statutory language implemented by SB 406 makes it abundantly clear the legislature intended for manufacturers to be able to acquire and process cannabis, and provide these products to patients, the potential for ambiguity or confusion over cannabis vs. cannabis-derived product should be specifically addressed in the context of manufacturers being able to acquire raw cannabis to make products for the program's patients. Should these new rules leave any doubt, the Department can expect more legal challenges from entities engaging in ongoing attempts to restrict patient access to medicine through outlets other than their own.

Thank you for your consideration,

Sean P. McAfee
The Law Office of Sean P. McAfee
9400 Holly Ave NE Bldg 4

7/11/2019

[EXT] Comment on proposed new NMAC 7.34.2.7, 7.34.3.7, ... - comment, MCP, DOH

Albuquerque NM 87122

(505) 944-2517

1(866) 241-0010 (fax)

smcafeelaw@gmail.com

Our office is paperless. Please send documents electronically. Our planet thanks you.

NOTICE OF PUBLIC HEARING

The New Mexico Department of Health (Department) will hold a public hearing on proposed amendments to various rule sections of the Department's Medical Cannabis Program rules at Parts 7.34.2, 7.34.3, and 7.34.4 NMAC. The hearing will be held on July 12, 2019 at 9:00 a.m. in the auditorium of the Harold Runnels Building, located at 1190 St. Francis Drive in Santa Fe, New Mexico.

The proposed rule amendments include:

- Revisions to nonprofit producer licensure requirements, including cannabis plant limits, licensing fee requirements, and the specification of certain quarterly reporting requirements;
- Revisions to standards concerning bases for disciplinary actions against licensed producers, and revisions to the fines applicable to licensed nonprofit producers;
- Revisions to personal production license (PPL) standards, including provisions regarding who may hold a PPL and where a PPL holder may grow cannabis plants;
- Addition of a licensing provision for school districts, public schools and charter schools, and their designated school personnel, to possess, store and administer cannabis for qualified students, in accordance with recent changes to the Public Schools Code;
- Modification of the patient enrollment period from the current one-year period to three years;
- Revision of certain hepatitis C eligibility requirements;
- Inclusion of certain annual submittal requirements for qualified patients;
- Removal of the 70% THC concentration limit for cannabis-derived products;
- Removal of the prohibition against certifications conducted by telemedicine, and inclusion of certain requirements applicable to such certifications;
- Revisions to the Medical Cannabis Advisory Board membership requirements; and
- Various revisions and additions to definitions in all three rule parts.

The legal authority for the proposed rule amendments is at NMSA 1978, Section 9-7-6(E), and NMSA 1978, Section 26-2B-7(A).

Free copies of the full text of the proposed rule amendments can be obtained online from the New Mexico Department of Health's website at <http://nmhealth.org/about/asd/cmo/rules/> or from Andrea Sundberg using the contact information below.

The public hearing will be conducted to receive public comment on the various proposed amendments to sections of Parts 7.34.2, 7.34.3, and 7.34.4 NMAC. Any interested member of the public may attend the hearing and submit data, views, or arguments either orally or in writing on the proposed rule amendments during the hearing. 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

All written comments must be received by 5:00 p.m. MDT on July 11, 2019. All written comments will be published on the agency website at <http://nmhealth.org/about/asd/cmo/rules/> within 3 days of receipt, and will be available at the New Mexico Department of Health Medical Cannabis Program for public inspection.

If you are an individual with a disability who is in need of special assistance or accommodations to attend or participate in the hearing, please contact Andrea Sundberg by telephone at (505) 827-2318. The Department requests at least ten (10) days advance notice to provide requested special accommodations.

DANIEL M. JACOBS

July 11, 2019

RE: Objection to Public Hearing and request that it be held in abeyance (Faulty Notice)

To Whom it may Concern,

My name is Daniel Jacobs, and I am the former Chief Records Custodian and Chief Privacy Officer for the New Mexico Department of Health (Retired) I am formally objecting to the New Mexico Department of Health, conducting the public hearing on proposed amendments to various rule sections of the New Mexico Department of Health's Medical Cannabis Program rules at Parts 7.34.2, 7.34.3, and 7.34.4 NMAC. This hearing is scheduled for July 12, 2019 at 9:00 a.m. in the auditorium of the Harold Runnels Building, located at 1190 St. Francis Drive in Santa Fe, New Mexico. I request that the hearing be held in abeyance until such time as proper notice to the general public is issued.

The "Notice" attached, provides contradictory information to the public about the period and time in which public comments may be submitted for consideration by the Hearing Officer. Pursuant to 1.24.25.11NMAC Rule Notice and 1.24.25.12 Written Comments.

Highlighted Text from NMDOH Notice states that the **public may not submit written comments after 5:00 pm July 11, 2019**, which contradicts the notification to the public that **they "member of the public may attend the hearing and submit data, views, or arguments either orally or in writing on the proposed rule amendments during the hearing."**

The Notice of Rulemaking to the general public must adhere to the requirements of the statute in so far as informing the public of the procedures they must follow in order to participate and have a voice in public policy, to do anything less would be detrimental. Good governance not only requires it but the public demand it. Therefore, I formally request that the public hearing be held in abeyance at such time as proper notice be issued.

Thank you,

Daniel Jacobs

DANIEL M. JACOBS



14-4-5.3. Public participation, comments and rule hearings. A. The notice of proposed rulemaking shall specify a public comment period of at least thirty days after publication in the New Mexico register during which a person may submit information and comment on the proposed rule. The information or comment may be submitted in an electronic or written format or at a public rule hearing pursuant to Subsection B of this section. The agency shall consider all information and comment on a proposed rule that is submitted within the comment period. B. At the public rule hearing, members of the public shall be given a reasonable opportunity to submit data, views or arguments orally or in writing.

The 2017 amendment, effective July 1, 2017, prohibited agencies from adopting rules until the public comment period has ended,

[EXT] Comment on Personal Production License/Licensed Non-Profit Producer Despencereries

PI [REDACTED]

Thu 7/11/2019 4:48 PM

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

Importance: High

To Those It May Concern,

I write submit this "comment" in reference to the new Mexico Department of Health Medical Cannabis Program, in particular to the Patient Personal Production License and the rules/regulations/laws in NMAC 7.34.3 & 7.34.4 and the Lynn and Erin Compassionate Act which governs the purchase of cannabis "seeds, clones, or plants from a Licensed Non-Profit Producer.

Let me begin with a little about myself [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED], I find that the NMCP's rules/regulations/laws are lacking affirmation when it comes to the Patient's Personal Production License "allowed" purchase of cannabis "seeds, clones, or plants from these Licensed Non-Profit Producers. For this program to work under the rules/regulations/laws of the NMCP, and in particular to the Personal Production License, the NM Licensed Non-Profit Producer(s) must make available the purchase of cannabis "seeds, clones, or plants" as referenced if the Personal Production License to be a valid "allowed" purchase.

You cannot purchase what the "Producers" do not make available. I pondered why the "Producers" would not want to make these purchases available and the only logical answer is, the "Producers" make far more money on Patients that purchase the Cannabis by the gram/oz then they would ever make on the seeds which allows the Patient to produce they on medical cannabis.

For that reason, I strongly submit that the rules/regulations/laws be updated to affirm the right of purchase of cannabis "seeds, clones, or plants" by the holder of a Personal Production License and that the NM Licensed Non-Profit Producer(s) must make the cannabis "seeds, clones, or plants" available at their dispensaries any time they have them on hand.

Respectfully submitted,



Daniel M. Jacobs

July 11, 2019

Ms. Andrea Sundberg

RE: **Public Comment for Proposed Rule Hearing July 12, 2019**

Dear Ms. Sundberg, please accept this as my official public comment on the proposed rule hearing of the Medical Cannabis Program.

Plant count,

The new rule proposes a plant count limit based primarily on two studies commissioned by the Department. The first study by RGL recommends a plant count based on a faulty premise that all PPL license holder will grow the maximum allowed under the rule. The RGL calculation removes that amount of grams from the total amount of cannabis in the market place as a base line to determine the number of plants a producer may grow. This study does not take into account that 26% (Research and Polling Report) of the PPL holders do not grow; so this amount would need to be subtracted from the original assumption, and the average number of yield by PPLs is much lower than the amount used in the calculation, which also should be adjusted. RGL based their assumption that all cannabis grown is usable (RGL report states that they did not consider quality of cannabis) this is a faulty premise that all cannabis grown will be female plants that give the maximum yield and quality for sale in the marketplace; that simply not possible.

The most reliable study that the DOH has is from Research and Polling which supports the position that there is not enough quality usable cannabis to meet the demand. The R&P report supports the position that an increase in plant count is necessary. R&P data shows that the primary purchase across the program is edibles rather than flower or bud.

The amount of useable cannabis available in any given grow in order to manufacture edibles is far less than the amount necessary to meet the current demand of the edible market. As more and more patients are added to the program; this amount continues to decrease even further based on consumption. The LNPP so will need to meet their patients' request who want more rather than less availability and variety, which is demonstrated in R&P's report. The lack of the availability restricts patients and the consequence is that, patients will have to go without the medication they need. This is likened to the pharmaceutical market where the price of a medication is not obtainable by the vast majority due to cost, and in this scenario cost is not the factor but the availability of material in order to manufacture the medicine that patients need is the primary barrier.



Either an increase in the total number of plants is needed in order to avoid a shortage in the marketplace of edible medicine or a new section creating a plant limit for the sole purposes of manufacturing edibles separate and apart from all other product produced. The R&P report supports this position based on the data showing often time edibles are not available or patients have to wait days and weeks in order to access their medicine solely due to the fact that there is not enough plant material to manufacture these items.



July 11, 2019

Re: Public Comment on Proposed Rules

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

Dear Ms. Sunberg,

Please accept the following comments from High Desert Relief, a LNPP for the New Mexico Medical Cannabis Program.

HDR has been serving the Medical Cannabis Program since 2010. Although these proposed rules are not perfect in our view, we completely support the MCP and appreciate the effort and attempts to continuously improve upon the program that has positively impacted the livelihoods of tens of thousands of New Mexicans.

7.34.4.7.YY “Seedling” Definition as it pertains to 7.34.3.8.A.(2) 1,750 plant count limit

We believe that the definition of a “seedling”, *“that is less than eight (8) inches in height,”* is arbitrary and a potential cause of concern in adhering to its compliance in the sense of cultivation. While the perceived intention of allowing LNPPs the flexibility needed to improve upon our production capabilities through the multiple advantages allotted by not adversely counting cuttings/seedlings against the proposed plant count, as written it could pose issues in adhering to this definition.

HDR propagates plants from mother plants in the vegetative stage to create new plants intended for cultivation. Most of these cuttings begin their growth at approximately 6” in height and are transplanting into grow medium for the rooting process. Once rooted, which typically occurs in 7-10 days, these starter plants see a rapid growth process and can quickly surpass the 8” in height essentially overnight. There is also a vast difference in growth rate depending on specific genetics, which are collectively grown together in cycles in groups of 300 plants currently. This variance could cause producers to be out of compliance within their chosen plant count unintentionally and unbeknownst to them because of this standard not based on definitive cultivation standards.

Our recommendation is that the proposed plant count limit of 1,750 be designated to mature/flowering plants only. This distinction between vegetative and “mature female plants” is very specific and intentional. This would allow LNPPs to take advantage of the intent of the ‘seedling’ guidelines that will result in a greater ability to selectively cultivate genetics for the patients that we serve and more importantly, provide a crystal clear definition/distinction and the appropriate application of such as it pertains to our chosen plant count.

7.34.4.8.W.(2) Non-Profit Producer License Fee Increase

While we realize that the MCP is funded entirely ‘internally’ from fees collected by LNPPs, Manufactures, Couriers, Approved Laboratories and PPL fees and other revenue sources to operate, the potential doubling of Licensure Fees for LNPPs appears to not be based on current or projected needs and is essentially arbitrary in nature. Additionally, this maximum renewal fee of \$180,000 for 1,750 plants must be directly passed onto the New Mexican citizens we are solely allowed to serve, qualified patients and their primary caregivers currently enrolled in the MCP.

There are currently 33 states that provide Medical Cannabis Programs and at this fee structure, New Mexico would become the 3rd highest renewal fee in the country and by far the most expensive west of the Mississippi River. Only Ohio and Michigan have higher annual renewal fees.

Specifically in our region, the following are the annual renewal fee requirements of the following states:

Arizona \$1,000
California \$77,905
Colorado \$5,300 (10,201-13,800 plants)
Nevada \$30,000
Oklahoma \$2,500 (unlimited plant count)
Oregon \$5,700
Washington \$1,480

As displayed, there is a considerable difference between the annual renewal fees of other successful state programs and the proposed fees of New Mexico. While we realize an increase of the allotted plant count is necessary to appropriately serve the qualified patients now and in the short-term future, we do not think there is a true correlation of doubling the MCP budget and its financial resources to oversee and ensure compliance. While we also realize that we are allowed to operate an expanded plant count while continuing to pay \$90,000 annually, we should not be monetarily penalized for exceeding that production limit to best serve those we entrusted to serve.

Additionally, to ramp up production, there is a substantial investment that must be incurred to do so. Not counting the physical building itself of our current production facility, we have already invested \$500,000 in its build-out and are anticipating outlaying another \$500,000 to expand again to take advantage of a larger plant count to be able to attempt to meet the current and real demand of the qualified patients that choose HDR as their provider of medical cannabis.

This excessive fee structure also prevents the ability of many of the small producers to expand their plant count to better serve qualified patients. It also invites outside entities from entering the MCP based on the need for increased funds for simple survival and to remain competitive with the LNPP community to better serve.

Our recommendation is that any increase of the renewal fee structure be based on the real time needs to support and appropriately fund the MCP and all the services it provides. While not privy to the annual budget of the MCP, our estimates of its \$3.2 Million annual budget seems reasonable and we recommend suspending the fee increase at this time and continue to require that annual renewal fee of \$90,000 for the 1,750 plants.

We feel like doubling the fees, again which are directly passed along to the qualified patients, was not based on needs of the program and in its essence, is an arbitrary fee structure that is excessive in comparison to other existing medical cannabis programs in operation around the country.

Thank you in advance for your time and consideration of our comments related to the proposed rule changes. Again we appreciate the effort, intention and research completed by the MCP to continue to improve upon the program that is truly making an lasting and effective impact on the well being of the citizens of New Mexico.

In Service,

A handwritten signature in black ink, appearing to read 'Drew Stuart', with a long horizontal line extending to the right.

Drew Stuart
Executive Director
High Desert Relief

The proposed rule and ancillary reports used to create the new rule is based on the presumption that those applying for the MCP can afford to purchase necessary medicine. Additionally, the report from the state of Oregon is based on statistical analysis of their recreational program and not a Medical Cannabis program, so the analysis is skewed by the fact that it does not take into account or even equate to NM based on population rates, rural locality, and economic issues faced by patients in NM.

What the rules does not state but allows is different that the intentions of the program.

PPL:

A holder of a PPL has the ability to grow 16 plants with 4 mature flowering plants. The yield of cannabis for the holder of a PPL is far greater than the access of a general patient, who is restricted to 8 ounces in a given 90-day period. Additionally, the holder of a PPL is not restricted from purchasing another 8 ounces in a 90-day period. This disparity equates to approximately 3 LBs for each PPL per 90 days verses 8 ounces in the same time period for a general patient. Essentially, if you have the economic means you will be able to benefit from the whole program but if you have economic barriers you are essentially treated differently.

Fees and set up:

The application fee for a PPL is a non-refundable \$30, the average cost to set up an indoor grow that comply with DOH rule is \$250.00 for security and materials. The average patient in the program does not have the financial resources to benefit from this section of the rule. The result like much of the rule does not benefit those who do not have economic means.

Facility:

The rule has required that PPL applicants obtain permission, if they rent or are living in a property that they do not own from their landlord to grow medical cannabis. Again, this show the disparity between those with means and those without. If you a patient in the program and you are renting an apartment from a commercial apartment complex, obtaining permission from a corporate entity that is in another states is virtually impossible, which further limi9ts the number of patients who can benefit from this section of the rule.

No Tracking:

The MCP dedicated no fewer than 9 pages in the new rule to outline requirements that LNPPs must adhere to, however, these same requirements are not imposed on the PPLs. The basic task for both a PPL and an LNPP is to grow cannabis for either personal PPL or commercial LNPP, yet not reporting requirements regarding the amount of usable cannabis is reported, no tracking "seed-to-sale" as required of LNPPs, no inspections, no quality assurance, and now the rule will allow those same PPLs to give cannabis to other qualified patients without any quality assurance.

Reynold Greenleaf & Associates, LLC

Comments for Proposed Rule Change Hearing Dated July, 12, 2019

7/11/19

Reynold Greenleaf & Associates, LLC (RGA) respectfully submits the following concerns regarding the proposed rule changes published by the Medical Cannabis Program (MCP) division of the New Mexico Department of Health.

7.34.4.8 PRODUCER LICENSING; GENERAL PROVISIONS:

A. The department may license two classes of producers:

(2) A non-profit producer that operates a facility and, at any one time, is limited to a combined total of no greater than ~~{2,500}~~ 1,750 cannabis ~~{mature female plants, seedlings and mature male}~~ plants, not including seedlings, ...

RGA agrees that the level of 1,750 cannabis plants is and appropriate level. Please see the Plant Count Formula for Determination of Appropriate Plant Count that we submitted to the MCP back in March of 2019.

7.34.4.8 PRODUCER LICENSING; GENERAL PROVISIONS: A. The department may license two classes of producers:

(1) A qualified patient or primary caregiver who holds a valid personal production license. 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.

RGA is concerned about the equality of rights among patients and possession levels. With the included language patients with a PPL would have additional rights of possession – allowing PPLs to possess unlimited amounts of cannabis due to the difficulty of discerning harvest totals and determining where cannabis product was produced. RGA suggests a universal possession limit extracted from the spirit of the law which provided all patients have an equal right to possess an amount of cannabis that guaranteed them ninety days of uninterrupted supply. This number should be determined through a process of discussion with patients, patient advocates and MCP officials. This total possession amount should be universally applied to all patients and enforced.

Y. “Manufacturer” means a ~~{business entity that manufactures cannabis-derived product that has been approved for this purpose by the medical cannabis program}~~ person that is licensed by the department to manufacture cannabis products; package, transport or courier cannabis products; have cannabis products tested by a cannabis testing facility; purchase, obtain, sell and transport cannabis products

to other cannabis establishments; and prepare products for personal production license holders.

RGA believes that granting PPLs the right to utilize manufacturers to generate Cannabis Derived Product is fundamentally correct, but we are very concerned with this language. PPLs could very well generate and possess up to twenty pounds a year. Converted to BHO or distillate cartridges could produce hundreds if not thousands of CDPs that could make their way on to the black market. The department should revisit this rule to clarify and track the manufacture of PPL materials to better provide public safety to the general public.

Other than the above mentioned items, RGA feels the proposed rule is a step in the right direction and feels that the Rule should pass and be promulgated.

Sincerely,

William Ford, Managing Partner, Reynold Greenleaf & Associates, LLC
Jacob White, Partner, Reynold Greenleaf & Associates, LLC
Chris Romero, Partner, Reynold Greenleaf & Associates, LLC

[EXT] Comments 2

Willie Ford <willie@reynoldgreenleaf.com>

Thu 7/11/2019 5:00 PM

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

NMDOH Formula for Plant Count Determination

$$(AEY \times \text{Plant Count}) \times NLP = (((TPE-PPP) \times LPA) \times PGR)$$

$$(1,589 \times Y) \times 35 = ((65,222 \times 920) \times 1.37\%)$$

$$\frac{(1,589 \times Y) \times 35}{35} = \frac{82,205,809}{35}$$

$$1,589 \times Y = 2,348,737$$

$$\frac{1,589 \times Y}{1,589} = \frac{2,348,737}{1,589}$$

$$Y = 1,478$$

TPE - Total Current Patient Enrollment - Total number of patients enrolled in the Program. (68,995)

PPP - Personal Production Patients - Estimated total of patients growing personal medicine. (3,773)

PGR - Current Patient Growth Rate - Current rate of program enrollment. (37%)

LPA - Legal Patient Allowance - The amount that a patient can legally purchase (per annum.) (920units)

AEY - Average Expected Yield - The average amount the DOH can expect a LNPP to produce. (1,589units/plant/year)

NLP - Number of Licensed Producers LNPP (35)

Plant Count - Plant Count Restriction (Unknown is represented as Y in Formula)



William Ford • Managing Director

Reynold Greenleaf & Associates

301 Eubank Blvd. SE • Albuquerque, NM 87123

505.463.3963 • willie@reynoldgreenleaf.com

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Patricia M. Monaghan
Attorney at Law

1212 Pennsylvania N.E.
Albuquerque, NM 87110
TriciaMonaghan@aol.com

Telephone: (505) 328-1061
Facsimile: (505) 255-4029

Via Hand Delivery on 7/12/19 to:

Hearing Officer at New Mexico Department of Health
Public Hearing on Proposed Amendments to Medical Cannabis
Program rules; Harold Runnels Building, Santa Fe, NM

Re: Comments on Amendments to Medical Cannabis Program Rules

Thank you for the opportunity to comment on the proposed rule changes. I am writing and testifying today as a New Mexico medical cannabis patient, advocate, and business attorney. I have been involved in our medical cannabis program since I started advocating for its passage in 2003. I petitioned the Medical Advisory Board at its first hearing in 2009, getting three conditions approved and becoming the 217th NM medical cannabis patient in February 2009. I also represented one of the first five nonprofit corporations to be licensed as a Licensed Nonprofit Producer (LNPP) in 2009. I am a member of the Board of Directors and Chair-Elect of the Cannabis Law Section of the NM State Bar and served as a member of the 2018-2019 NM Cannabis Accessibility and Affordability Task Force. My law practice for the past eleven years has concentrated on representing and advising licensed medical cannabis producers, manufacturers and applicants under New Mexico's Lynn and Erin Compassionate Use Act (LECUA).

I completely support and adopt Secretary Kunkel's stated mission in her June 11, 2019 announcement of this meeting: *"Our focus with this is to better provide a medical cannabis system that guarantees safe access for patients to safe medicine. We want to assure patients have enough medicine both now and in the future as well as in forms that make the most sense for the very conditions they're treating."*

The most important stakeholders in our Medical Cannabis Program (MCP) are the persons for whom the program was created, the patients:

The purpose of the Lynn and Erin Compassionate Use Act is to allow the beneficial use of medical cannabis in a regulated system for alleviating symptoms caused by debilitating medical conditions and their medical treatments. NMSA § 26-2B-2, "Purpose of act."

The rules need to be designed to *"provide a medical cannabis system that guarantees safe access for patients to safe medicine."* And *"to assure patients have enough medicine both now and in the future . . . ,"* as Secretary Kunkel eloquently articulated.

With Secretary Kunkel's focus of guaranteeing safe access for patient to enough medicine, these revised rules need to be amended for the benefit of patients by ensuring access and availability. That can be accomplished by licensing more and diversified producers, growers, distributors or dispensaries. The increase in licensing of providers can also be encouraged by reducing the application fee for nonprofit producers' licenses, which is unchanged from its draconian increase the last time these regulations were amended in 2015, and instituting low application fees for more and diverse medical cannabis industry providers or licensees.

The nonprofit producer application fee was \$100 in 2009 and 2010 when the first 25 Licensed Nonprofit Producers (LNPPs) were awarded their licenses. The fee was increased to \$10,000 for the next 12 LNPPs licensed in 2015 under Governor Martinez' administration. This fee is exorbitant and anti-progressive. It should be significantly decreased to eliminate barriers to entry into the medical cannabis market and increase access for patients. And new fees for new licensees need to be appropriate. The current application fees are unreasonable and unjustified.

The Department of Health and others have identified the most urgent problem facing the MCP today as inadequate supply. Inadequate supply imposes multiple hardships to patients by increasing the cost of their medicine, forcing some patients to do without their medicine, or go to the black market for it. This shortage results in both the lack of availability of legal medical cannabis and excessive prices for it, especially in the rural markets. Court decisions in 2014 and 2019 resulted in forced increases to the plant count limits of LNPPs.

However, increases in plant count limits are neither the exclusive nor preferential answer for patients. Instead, the licensing of more LNPPs coupled with the disintegration of the medical cannabis industry by licensing new growers and distributors separately is much more advantageous to the patient. Under the current rules a LNPP must both produce and distribute medical cannabis. With vertical integration eliminated, it will be less expensive to enter the market and will allow more microbusinesses, mom and pop shops, to enter the medical cannabis market. That would also create a more competitive environment leading to more innovative products and lower prices for patients.

Exorbitant application fees and the completely vertically integrated medical cannabis industry is contradictory to the enabling statute, the LECUA. Instead of allowing the beneficial use of medical cannabis, they greatly impede the production of medical cannabis. These fees and mandatory vertical integration, lack of micro-business are clearly not based on nor consistent with the legislative intent. Regulations should be promulgated to create licenses for businesses not vertically integrated, that could either produce or distribute medical cannabis, but not be required to complete both.

The DOH has ample authority and direction to implement my suggestions. Under Senate Bill 406, Section 8, a new section of the LECUA is to be enacted to read: . . . " By 12/20/19 secretary of health shall adopt and promulgate rules to establish fees and licenses for

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cannabis producers, manufacturers, couriers, testing facilities, **or any other cannabis establishments whose operations are authorized pursuant to the LECUA.** . . .(D) The Department shall administer licensure for medical cannabis program activity provided for in the LECUA, which shall include . . . (5) **any other activity** or person as deemed necessary by the department.”

The following is more of a minor editorial comment, however it is important that our regulations use correct grammar and punctuation and are consistent with our statutes: **7.34.4.7 (FF) “Non-Profit Producer.”** Nonprofit is one word without a hyphen. Please see Section 53-8-1 *et seq.* NMSA 1978, “Nonprofit Corporations.” There may be conflicting opinions about the correct spelling of Nonprofit, but New Mexico’s regulations should at least be consistent with New Mexico’s statutes and our Nonprofit Corporations’ statute does not use a hyphen.

Finally, I would also support Dr. Steven Jennison’s [the first medical director of the medical cannabis program from 2007 to 2010, who also served on the Medical Advisory Board and as its Chair for many years] suggestions in his written comments submitted 7/8/19 Re: Medical Advisory Board – roles, responsibilities and authority. Specifically, “1) the Secretary of Health should have a limited defined time within which to act upon the recommendations of the Medical Advisory Board; and 2) The DOH should respect the statutory authority of the Medical Advisory Board to provide consultation on a) changes to patient enrollment eligibility; and b) changes in allowed quantities and preparations of cannabis available to patients in the program.” *See* Steven Jennison, MD, NRP comments RE Medical Advisory Board – roles, responsibilities and authority, 7/8/19.

In conclusion, the regulations need to be revised to reflect and enable the goals of the LECUA and guarantee safe access to enough safe medicine for patients throughout New Mexico. I appreciate the time and attention that you and others in the Department tasked with this rulemaking will give my comments. Please contact me should you have any question. Thank you.

Sincerely,

Patricia M. Monaghan

cc: MCP.comment@state.nm.us