
Via Electronic Mail Only

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July 31, 2019

Re: Proposed Medical Cannabis Rule Amendments

Dear Mr. Erickson:

This letter is written on behalf of the New Mexico Department of Health in response to your letters dated July 19 and July 25, 2019, in which you requested information from the Medical Cannabis Program regarding public comments received concerning the Department's proposed amendments to the Medical Cannabis Program rules 7.34.2, 7.34.3, and 7.34.4 NMAC. Below are the Department's responses to public comments that were made in the course rulemaking that the Department recognizes to be germane to the amendments that have been proposed.

1. Regarding the definition of "seedling"

The Department has proposed to permit licensed nonprofit producers (LNPPs) to possess an unlimited supply of "seedlings", and has proposed to define the term "seedling" as "a cannabis plant that has no flowers and that is less than eight (8) inches in height". The Department received public comments from various individuals, including Drew Stewart of the LNPP High Desert Relief and David Belcher of the LNPP Pecos Valley Production, that the 8-inch limit for seedlings is too limiting. Some LNPPs commented that they tend to grow plants from clones (cuttings from plants that are immersed in water to grow roots), and that these clones are typically close to the 8-inch limit when they're cut from the host plant, so the benefit of unlimited seedlings would be minimal if they are limited to 8 inches in height. Some commenters requested that the Department remove all size restrictions from the definition of "seedling", and rely solely on whether a plant is flowering.

One of the purposes of clearly defining the plant limit and the limits on what will be deemed a "seedling" is to ensure that the Department of Health and law enforcement are able to use clear parameters to determine LNPPs' compliance with applicable rules, when counting plants at a production facility. The 8-inch limit furthers that purpose, while also providing nonprofit producers greater flexibility than under previous rules. In contrast, it would be significantly more difficult for the Department and for law enforcement to quickly differentiate between large non-flowering plants and large flowering plants, particularly in the setting of a large growing facility. The Department wishes to ensure that licensees are able to clearly distinguish between their plants and seedlings, to ensure that they stay within their limits.

However, the Department understands the concerns that have been raised regarding the size limit being too restrictive. For that reason, in response to the public comments received, the Department

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intends to revise the proposed definition of “seedling” to establish a 12-inch height limit. A 12-inch standard should mitigate some of the concerns raised regarding the 8-inch proposal, while still meeting the Department’s objectives. The 12-inch standard is also consistent with the requirements of various medical cannabis programs in other states, including those of Maine, New Hampshire, New Jersey, and Pennsylvania.

The Department also received comment that the proposed definition of “seedling” does not identify how the height of a seedling would be measured. In consideration of that comment, the Department proposes to modify the proposed definition as follows:

“Seedling” means a cannabis plant that has no flowers and that is less than twelve (12) inches in height, as measured vertically in the plant’s natural position from the uppermost part of the root system (or from the soil line, if the plant is planted in soil) to the tallest point of the plant.

2. Regarding the proposed changes in renewal fees for LNPPs

The Department has proposed to create new licensure fees for LNPPs. These fees are proposed partly in recognition of the change to plant limits for LNPPs, and also in recognition of anticipated increases to costs for operation of the Medical Cannabis Program. Some commenters described the fee changes as an “increase” to fees, a characterization that the Department disputes. The fees are substantially less per plant than what LNPPs have historically paid (between \$80 and \$102.85 annually per plant vs. the previous fee of \$200 per plant). The fees also accomplish the objective of enabling smaller producers with fewer resources to grow 500 plants (2,000 plants in the course of a year, assuming four harvests annually) for \$40,000, which is less than half of the \$90,000 fee that producers previously paid for 450 plants. The fee structure requires that producers who grow more plants pay a greater fee, although the cost-per-plant remains substantially less at an average of \$102.85 for 1,750, or about \$25 per plant per year assuming four harvests annually. The Department believes this to be an equitable fee that appropriately factors the differing sizes and resources of LNPPs. By contrast, the LNPP Ultra Health recommended that the Department institute a \$30,000 fee for 500 plants and \$105,000 for 5,000 plants. This would result in per-plant fees of \$60 per plant for producers who license at 500 plants, and \$21 per plant for producers who license at 5,000. This fee structure would benefit larger producers and disadvantage smaller producers. This is not the Department’s objective in instituting new fees.

The Department does not consider the proposed LNPP licensing fees to be exorbitant. The Medical Cannabis Program is funded entirely by licensing fees, and primarily by LNPP licensing fees. LNPPs have considerable revenues, as reflected in quarterly reports that show that the total combined reported revenue of all licensed nonprofit producers in 2018 exceeded \$115 million. The LNPP Ultra Health reported the highest revenues for the year, at over \$16 million. The lowest revenue reported by any of the LNPPs (for Budding Hope) was nearly \$500,000 for the year.

Some commenters expressed that the proposed fees exceed the Department’s costs in operating the Medical Cannabis Program. Although it is difficult to determine the amount of fee revenue that the Program will receive under the proposed rule, the Department anticipates that the fees will not significantly exceed the Program’s anticipated operating expenses, if they exceed the

Program's expenses at all. Some LNPP representatives estimated that fewer than half of the licensed LNPPs will choose to become licensed to grow 1,750 plants in the next licensure period. Some producers will likely delay expansion to the maximum plant limit until they have built out increased infrastructure (additional grow locations, grow lights, plumbing, etc.). The Medical Cannabis Program's current operating budget (covering payroll, contracts for services and temp contract labor, and legal services, and costs for vehicles, office supplies, etc.) is approximately \$3,200,000. The Department anticipates that the Program's expenses will increase, due in part to continued expansion of the Program, as well as changes adopted in SB406 in the 2019 legislative session. Among other expenses, the Program plans to create 8 additional full-time employee (FTE) positions in its Patient Services section, and 4 additional FTE positions in its Licensing and Compliance section, at a combined cost of approximately \$600,000. There are currently 34 licensed nonprofit producers. Assuming that 16 licensed nonprofit producers decide to grow 1,750 plants, and that the remaining producers are equally divided between 500 and 1,000 plants, revenue from LNPP licensing fees would not exceed \$4,050,000. This figure would be close to the Program's anticipated expenses, although it is also possible that the Program will see less revenue as a result of LNPPs deciding to become licensed at lower plant limits.

3. Regarding the proposed LNPP plant limit of 1,750

The Department has proposed to increase the plant limit for LNPPs from the previous 450 plants per producer, to 1,750 plants per producer, with provisions for LNPPs to request further increases in the future. The rationale for this proposal is as stated in the Department's memorandum at Exhibit 5.

Several LNPPs expressed support for the proposed plant limit at the rule hearing. Some LNPPs requested that the plant limit be further increased. The Department disagrees that the LNPP plant limit should be further increased. The Department anticipates that the 1,750 plant limit will not only meet demand, but will significantly exceed demand for the foreseeable future. As noted in the memorandum at Exhibit 5, this conclusion is supported by reference to the results of the patient and producer surveys, as well as the industry reports from R. Greenleaf and Kelly O'Donnell. Assuming that LNPPs engage in four harvests per year on average (a figure supported by both the producer survey and national standards), the 1,750 plant limit will result in production of 7,000 plants, a figure that exceeds all requested figures. Furthermore, the proposed plant limit is not static, but includes provisions for the increase of a nonprofit producer's plant limit based on demand. The Department also retains the ability to license additional LNPPs to increase available supply.

The LNPP Ultra Health and Kelly O'Donnell, an economist who has testified on behalf of Ultra Health in previous litigation, have requested a maximum per-producer plant limit of 5,000 at any given time. At that number, when factoring four harvests per year, the 34 currently licensed LNPPs would each be able to harvest 20,000 mature plants per year; meaning that collectively the 34 LNPPs would have the ability to harvest 680,000 mature plants. Based on Ultra Health's self-reported yields of cannabis produced per plant (1.25 pounds of cannabis flower yield per plant), allowing each LNPP to harvest 20,000 plants each would result in a total annual yield of 850,000 pounds of medical cannabis. However, the O'Donnell report stated that the annual yield needed to satisfy current maximum patient demand (at 920 grams of cannabis per year for 70,600 qualified

patients) is 143,195 pounds of cannabis per year. Allowing LNPPs to grow 850,000 pounds of cannabis per year would thus result in an estimated surplus of 708,800 pounds of cannabis, which is about five times the amount of cannabis needed to meet the maximum possible demand for 70,600 qualified patients. These numbers do not factor in the effect of harvests from personal production license holders. Even if the LNPPs grew half that quantity annually (425,000 pounds of cannabis per year), there would still be a surplus of 283,000 pounds of cannabis in the marketplace.

It is important to note that qualified patients consume considerably less medical cannabis than the amount permitted under the “adequate supply” use and possession limit of 230 grams/units per three months, or 920 grams/units per year. Based on the recent patient survey, patients consume on average 50.4 grams of dried flower product in a three-month period. They also consume a combined total of about 12 units of concentrates, edibles, and topical products in that period. Based on the equivalencies that were used in the Freedman & Koski report (at Exhibit 8, pp. 3-6) to identify the quantity of flower material needed to make those cannabis-derived products, that would amount to an additional 65.128 grams, for an average total consumption of 115.53 grams in three-month period. That is approximately 50% of the maximum supply that a qualified patient is permitted to possess and consume in three months. In fact, the Freedman & Koski report identified that current demand could be met with a plant limit of 543 plants per each of the 34 LNPPs.

The LNPP Ultra Health further suggested, at page 2 of their written comments, that the figure of 3,016 that was estimated by LNPPs in the producer survey as necessary to meet demand should not be divided by the number of harvests per year, because “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’.” The survey question asked, “How many plants do you estimate your company needs to grow, per year, in order to meet current patient demand (including products your company does not currently produce)?” Ex. 7 at 45. This question is not ambiguous. Moreover, to interpret this question as asking how many plants should be kept in circulation at any time would render the words “per year” meaningless.

Kelly O’Donnell stated in her comments that LNPP plant limits should factor various theoretical measures of demand, including what she described as “pent-up” demand, and further indicated that Judge Thomson had endorsed this view in his Order of 11/1/18, which is contained at Exhibit 11. That is incorrect. Judge Thomson did not make any findings regarding the alleged existence of “pent-up demand”, and did not hold that the Department of Health is obligated under the law to meet this or any other theoretical measure of future demand. The Court’s holding was that the static 450-plant limit was not adequately tied to demand in the Program, and was based on outdated data. The Court held that the Department can set a *per se* plant limitation on producers that is based on current data, and that is what the Department has done in this rulemaking.

It is also significant that none of the analyses of supply and demand concerning the Medical Cannabis Program have factored the burgeoning hemp program in New Mexico. Pursuant to the U.S. Farm Bill of 2018, hemp-derived products were removed from Schedule I status under federal law, and rules have been adopted for the cultivation and laboratory testing of hemp in New Mexico. Hemp-derived products can include cannabidiol (CBD) oils, tinctures, salves, and other products.

The Department anticipates that the increased availability of these cannabis-derived products outside of the Medical Cannabis Program may reduce demand for similar cannabis products within the Program.

4. Regarding the proposed increases to monetary fines for commercial licensees in 7.34.4 NMAC

The Department has proposed to increase the maximum monetary fines for commercial licenses at 7.34.4.24 NMAC. Some commenters expressed that they believe the fines are too high or beyond the Department's legal authority. As expressed in the memorandum at Exhibit 5, the Department is concerned that the current fines are insufficient to either discourage noncompliance or encourage compliance by licensees with DOH regulations. The proposed fine structure is designed to allow the Department to vary the amount of a fine depending on its severity, in view of individual facts and circumstances. The Department believes that the identified maximum fines are appropriate and consistent with its lawful authority.

In written comments, the LNPP Ultra Health claimed that the holding in *Marbob Energy Corp. v. New Mexico Oil and Conservation Comm'n*, 2009-NMSC-013, 146 N.M. 24, indicates that the Department cannot impose monetary fines on licensees. The Department disagrees with this comment. The *Marbob Energy Corp.* case did not stand for this proposition, but instead relied on a holding that the New Mexico Attorney General held more explicit statutory authority to impose fines on licensees than did the Oil Conservation Commission. In contrast to the facts at issue in the *Marbob Energy Corp.* case, the Attorney General does not possess statutory authority to impose fines on medical cannabis licensees for violations of Department of Health rules.

The Department also disagrees with the recommendation that it should allow licensees to cure all deficiencies prior to being penalized. Such a practice would not discourage non-compliance with licensing requirements, but would actually encourage non-compliance, as it would enable licensees to violate Department rules without repercussion.

5. Regarding the proposed changes to the definition of "manufacturer"

The Department has proposed to amend the definition of "manufacturer" to mirror the definition of "manufacturer" that was recently included in statute at NMSA 1978, § 26-2B-3 via Senate Bill 406 of the 2019 legislative session. "Manufacturer" is proposed to be defined as a "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."

Sean McAfee, counsel for the New Mexico Beneficial Products Manufacturers Cooperative Association, requested in written comment that the Department amend the proposed definition of "manufacturer" to include a statement that manufacturers can "purchase, obtain and transport cannabis for the purpose of manufacturing cannabis-derived product". The Department agrees that it is the expressed intention of the Legislature that licensed manufacturers should be able to obtain cannabis from producers and manufacture cannabis-derived products from that cannabis.

The ability of manufacturers to obtain cannabis is implicit in their authority to manufacture cannabis-derived products, which implicitly requires the receipt of cannabis for that purpose. This is also consistent with longstanding Department rules regarding manufacturers. However, whereas the statute permits manufacturers to purchase cannabis-derived products from LNPPs, it does not state that manufacturers are permitted to purchase cannabis. The expression “cannabis product” was defined under SB406 of the 2019 legislative session, as follows:

H. "cannabis product": (1) means 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[.]

NMSA 1978, § 26-2B-3(H). Given the content of this definition, and given the use of this particular expression in the statute, the Department does not believe that manufacturers are authorized to purchase cannabis, rather than cannabis products, from LNPPs. However, the Department anticipates that the distinction between “cannabis” and “cannabis products” will be of little practical consequence, as manufacturers will enter into contracts with LNPPs to transfer ownership of cannabis-derived products to manufacturers upon the manufacturers’ creation of the products.

William Ford of the LNPP R. Greenleaf commented that, with personal production license (PPL) holders now being permitted to possess all of their harvest, and with manufacturers being permitted to receive cannabis directly from patients for processing into cannabis-derived products to be returned to the patients, it is possible that a patient who possesses a PPL could have significant quantities of butane hash oil or other derived products manufactured, that exceed the adequate supply limit. As the statutory text is written, a PPL holder can possess all of the cannabis from their harvest, and a patient can have cannabis-derived products created by manufacturers from their cannabis. As such, the Department does not believe that it has authority under statute to limit the quantity of derived products that a patient has manufactured by a licensed manufacturer from the patient’s PPL grow. To limit the quantity of products derived from a PPL holder’s harvest would seem to be inconsistent with the text of the statute. Also, while it is theoretically possible that a PPL holder could have significant quantities of cannabis-derived products manufactured for them, PPL holders typically do not possess the same degree of horticultural expertise as LNPPs, and their yields per plant tend to be drastically less than that of LNPPs, as reflected in the recent patient survey at Exhibit 6.

Some commenters suggested that licensed manufacturers should be compelled to be nonprofit corporations, as producers are under Department rule. Since the inception of the New Mexico Medical Cannabis Program, the Department has required that licensed commercial producers of medical cannabis be nonprofit corporations. This was required in recognition of the purpose of the statute, and the fact that producers control the medical cannabis marketplace, including all production and distribution of cannabis in the market. Producers also dictate the prices that qualified patients pay for cannabis products. By contrast, licensed manufacturers do not control the medical cannabis market, do not dictate prices of products in the market, and do not have the same revenues or resources as commercial producers, but tend to be considerably smaller enterprises. There are also fewer licensed manufacturers in operation than LNPPs. Thus, the

motivations behind requiring that commercial producers be nonprofit are not shared across all license designations, and the licensees are not “similarly situated”. For these reasons, at this time, the Department does not intend to require that manufacturers or licensees other than LNPPs be nonprofit companies.

6. Regarding the proposal to add a definition of “non-profit producer”

The Department has proposed to add a definition for the expression “non-profit producer”, defining the expression to mean “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.” The Department has proposed to add this definition to reflect longstanding requirements of Department rule concerning LNPPs.

The Department received comment from the LNPP Ultra Health that the Lynn and Erin Compassionate Use Act does not require that commercial cannabis producers be nonprofit corporations, and that there is no statutory support for DOH’s requirement that commercial producers be nonprofit. Once again: since the beginning of the New Mexico Medical Cannabis Program, the Department has required that commercial producers of medical cannabis be New Mexico nonprofit corporations. The Department has required this in furtherance of the stated purpose of the Lynn and Erin Compassionate Use Act, 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 1978, § 26-2B-2; *see also* NMSA 1978, § 26-2B-7(A) (“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 stated purpose of the Lynn and Erin Compassionate Use Act is not to enable for-profit corporations to enrich themselves at the expense of qualified patients, but rather, to benefit qualified patients, in a regulated system. Requiring that commercial producers of medical cannabis be New Mexico nonprofit corporations is intended to further the statute’s purpose, by requiring that commercial producers comply with New Mexico nonprofit laws, and by attempting to diminish the profit motivations of these licensees. This is clearly within the Department’s authority under the statute at NMSA 1978, § 26-2B-7, which not only requires that the Department promulgate rules to further the statute’s purpose, but grants broad discretion to the Department to “identify requirements for the licensure of cannabis producers and cannabis production facilities”.

It is also important to note that, despite the recent enactment of changes to the statute, there has been no expression of disagreement by the state Legislature with the Department’s rule requiring that commercial producers of medical cannabis be New Mexico nonprofit corporations, despite the existence of the nonprofit requirement in Department rule for over a decade. This demonstrates the Legislature’s acquiescence to the nonprofit requirement in Department rule. As shown in the case of the recent statutory amendment in SB406 that prohibits the Department’s previous 70% THC limit for cannabis-derived products: when the Legislature disagrees with a rule of the Department, it expresses that disagreement by affirmatively prohibiting the Department’s rule, and not by omitting a regulatory requirement in a statutory definition. To interpret the omission of the nonprofit requirement from the statutory definition of “cannabis producer” in this way not only disregards the broad scope of the Department’s authority to set regulatory requirements that further

the purpose of the statute, but it ignores the long history of this requirement in Department rule and the actual practice of the New Mexico Legislature.

The Department also received public comment that the definition should more closely reflect the definition of “cannabis producer” that has been added to NMSA 1978, § 26-2B-3 via Senate Bill 406 of the 2019 legislative session. In consideration of that comment, the Department proposes to amend the proposed definition of “non-profit producer” to state:

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 possess, produce, dispense, distribute and manufacture cannabis and cannabis products and sell wholesale or by direct sale to qualified patients and primary caregivers.

7. Regarding requirements for the submittal of certain medical records in support of patient applications

The Department has proposed to amend 7.34.3.8 NMAC to specify qualifying medical conditions that were recently included in statute via SB406, and also to specify medical conditions that were recently approved by the Cabinet Secretary for participation in the Program. Among the statutory conditions listed at the proposed 7.34.3.8(A) NMAC, the Department has proposed to include text requiring the submittal of medical records for post-traumatic stress disorder, chronic pain, painful peripheral neuropathy, and inflammatory autoimmune-mediated arthritis. The LNPP Ultra Health commented that these requirements, as applied to the qualifying conditions of arthritis, PTSD, and chronic pain, violate the Compassionate Use Act. This assertion is incorrect.

The Department of Health is statutorily required to “verify” the information contained in an application, and as such, the Department is authorized to obtain applicant medical records concerning an applicant’s asserted qualifying diagnosis. NMSA 26-2B-7(C) states in part, “The department shall verify the information contained in an application submitted pursuant to Subsection B of this section....” Requiring the submittal of medical records that confirm a diagnosis identified in a patient application is part of the verification process.

The LNPP Ultra Health also commented that these regulatory requirements are prohibited by an order of the Santa Fe District Court (J. Thomson) in the case of *Carola Kieve v. New Mexico Department of Health*, no. D-101-CV-2014-00140. That assertion is also incorrect. In the final order from the *Kieve* case, the District Court specifically held, at paragraph 38 on page 15: “It is within the Department’s authority in verifying the application to ask for a medical record that confirms the diagnosis.”

8. Regarding the proposal to require that destruction of usable cannabis be videotaped

The Department has proposed to add a provision at 7.34.4.8(M) NMAC to require that LNPPs document the destruction of usable cannabis by videotaping. The Department received comment from Ben Lewinger, Executive Director of the New Mexico Cannabis Chamber of Commerce, requesting clarification regarding what is meant by “destruction” in this context. The Department

responds that destruction in this context refers to destroying usable cannabis so as to waste the usable cannabis. Typically this is done by LNPPs when a plant is sick, or when plant material is moldy or has some other contaminant that requires that it be destroyed. Destruction in this context does not refer to the act of converting cannabis plant material into a cannabis-derived product.

9. Regarding the proposed quarterly reporting requirements

Representatives of the LNPP Ultra Health commented that the quarterly reporting requirements that have been proposed to be identified at 7.34.4.23 NMAC are too onerous, and that this information is already entered by LNPPs into the BioTrack tracking system. Much of the information proposed to be added in this passage of the rule has already been required as a matter of practice to be included in LNPPs' quarterly reports. While it is true that some of this information is entered into BioTrack, the information in BioTrack is not readily accessible to the Department and is not readily compiled. The Department considers this information to be valuable for the Department's monitoring and regulation of the Program, and does not believe that the proposed quarterly reporting requirements are especially onerous for LNPPs.

In closing, the Department received many public comments in the course of this rulemaking that, although not germane to the proposed amendments, is nevertheless valuable to the agency in its consideration and formulation of its policies and future rules for the Medical Cannabis Program. The Department greatly appreciates the interest and input that it received from stakeholders and members of the public, and thanks the commenters for their thoughtful deliberations and concern for this medical program, which has brought relief to thousands of patients with debilitating medical conditions.

Please do not hesitate to contact me if you have any further questions.

Sincerely,



Chris D. Woodward
Assistant General Counsel