

Summary of Medical Cannabis Program Rule Amendments

7.34.2 NMAC:

7.34.2.7 NMAC: Amendments to definitions; identical to proposed amendments of 7.34.3.7 and 7.34.4.7 NMAC.

7.34.2.8 NMAC:

(A): Number of Medical Cannabis Advisory Board members changed from 8 to 9; specialty requirements removed; organizations that can propose members to be appointed expanded. These amendments are made pursuant to statutory revisions contained in SB406. *See* NMSA 1978, § 26-2B-6.

(D): Number of Medical Cannabis Advisory Board members changed from 8 to 9 (see (A) above).

7.34.2.10(H)(1) NMAC: Quorum of Medical Cannabis Advisory Board changed from 3 to 5. This amendment is made pursuant to a statutory revision in SB406. *See* NMSA 1978, § 26-2B-6.

7.34.3 NMAC:

7.34.3.7 NMAC: Amendments to definitions; identical to proposed amendments of 7.34.2.7 and 7.34.4.7 NMAC.

7.34.3.8 NMAC:

(A): Amended to reflect statutorily approved conditions as revised by SB406; and also amended to include qualifying medical conditions recently approved by the Department. The Department recently approved autism spectrum disorder, Friedrich's ataxia, Lewy body disease, spinal muscular atrophy, Alzheimer's disease, and opioid use disorder as conditions qualifying for enrollment in the Medical Cannabis Program.

(C): Amended to specify that a written certification be included with a patient's application for enrollment.

(D): Amended to reflect annual submittal requirements specified in SB406.

7.34.3.9 NMAC:

(C): THC concentration limit removed to reflect statutory amendments from SB406.

(D): Medical exception amended to remove references to THC limit, per statutory amendment in SB406.

7.34.3.10 NMAC:

(C): Fee for replacement of registry identification card is removed, reflecting a statutory amendment in SB406. Note that this is not the same as the personal production license fee, which remains in effect.

(D): Reference to federal issued photo identification card is removed. The Department is not aware of any federally-issued cards that can be used to verify New Mexico residence; thus, the proposed amendment.

(E)(1): Reference to federally-issued i.d. cards removed, for reasons described in (D) above.

(G)(3): Statement that primary caregiver cannot independently produce medical cannabis is deleted. This is based on a statutory revision in SB406 that permits a primary caregiver to grow cannabis on behalf of a qualified patient. *See NMSA 1978, § 26-2B-3(R).*

(H)(3): Amendment to specify that a practitioner may issue a written certification of a patient on the basis of telemedicine if the practitioner has previously examined the patient in person. This amendment is based on a provision within SB406. *See NMSA 1978, § 26-2B-3(V).*

7.34.3.11 NMAC:

(B): Enrollment period for a qualified patient or primary caregiver is revised from one year to three years. This is based on a statutory revision from SB406. *See NMSA 1978, § 26-2B-7(D).*

(E): Reference to one year enrollment period changed to three years (see (B), above). Requirement that certifications be obtained within 90 calendar days from expiration of a registry identification card is modified to 90 days prior to submission of the patient's application. This edit is proposed to assist the Department in verifying that an applicant's diagnosis is current and correct, and also to afford patients greater flexibility in the event that there is a gap between expiration of their enrollment and submittal of a renewal application.

(H): Reference to fee for replacement registry i.d. card removed, per a statutory amendment in SB406. *See NMSA 1978, § 26-2B-10(C).*

7.34.3.15(D) NMAC: References to potential for criminal prosecution or civil penalty for possession of cannabis in a school bus or public vehicle, or on school grounds or property, removed to reflect a statutory amendment in SB406. *See NMSA 1978, § 26-2B-5(A)(3).*

7.34.3.17(B) NMAC: Statement added that a qualified patient or primary caregiver can collectively possess a qualified patient's harvest of cannabis from a personal production license grow. This is based on text added to statute in SB406. *See NMSA 1978, § 26-2B-4(A).*

7.34.3.19 NMAC: Removal of prohibition against transfer of cannabis from a qualified patient or primary caregiver to another qualified patient or primary caregiver, in accordance with statutory revisions in SB406. See NMSA 1978, § 26-2B-3(R).

7.34.4 NMAC:

7.34.2.7, 7.34.3.7, and 7.34.4.7 NMAC (identical amendments to definitions):

Advisory board: amended the number of members from the previous 8 to 9, based on statutory changes enacted by the passage of Senate Bill 406 (SB406) from the 2019 legislative session; and removed fields of specialty based on the same. See NMSA 1978, § 26-2B-6.

Approved laboratory: amended based on statutory definition from SB406. See NMSA 1978, § 26-2B-3(I).

Cannabis: amended based on statutory definition from SB406. See NMSA 1978, § 26-2B-3(B).

Debilitating medical condition: amended based on statutory definition from SB406. See NMSA 1978, § 26-2B-3(J).

Non-profit producer: added definition that reflects existing producer licensure requirements in NMDOH rule.

Personal production license: amended based on statutory definition from SB406. See NMSA 1978, § 26-2B-3(R).

Telemedicine: added based on statutory definition from SB406. See NMSA 1978, § 26-2B-3(Z).

7.34.4.8 NMAC:

(A)(1): Added “primary caregiver” to reflect statutory amendments from SB406, and removed prohibition against primary caregivers independently growing medical cannabis for a qualified patient, also based on SB406. See NMSA 1978, § 26-2B-3(R).

(A)(2): Proposed plant limit:

On November 1, 2018, the First Judicial District Court (J. Thomson) issued an order in the matter of *Nicole Sena and New Mexico Top Organics – Ultra Health v. New Mexico Department of Health and Lynn Gallagher*, case no. D-101-CV-2016-01971, in which the Court DOH enjoined the Department of Health from enforcing the 450-plant limit for licensed nonprofit producers that applied under a previous iteration of 7.34.4.8(A)(2) NMAC, and invalidated that version of the rule. However, the Court expressly held that the Department has authority to regulate the medical cannabis industry by means of a plant limit, as long as the limit is based in fact and does not impede the purpose of the Lynn and Erin Compassionate Use Act. The Court stayed imposition of the injunction until March 1, 2019 to allow the Department time to adopt an amendment to the rule.

On March 1, 2019, DOH amended 7.34.4.8.A(2) NMAC via an emergency rulemaking to temporarily increase the plant limit for each producer from 450 plants to 2,500 plants, to ensure that a plant limit remained in place after the expiration of the stay. The temporary increase to the plant limit was adopted based partly on consultation from licensed nonprofit producers.

The Department contracted with Research and Polling, Inc. to conduct surveys of qualified patients and licensed nonprofit producers, in part, to gather more information relevant to the evaluation of supply and demand within the Medical Cannabis Program. The Department also contracted the cannabis consulting firm of Freedman & Koski, Inc., which evaluated and summarized the findings of the patient and producer surveys as well as two reports from industry representatives in a written report (“Freedman report”).

The Freedman report identified various methods of measuring demand within the Program and specified the number of plants that would be necessary to satisfy each of those measures. The first measure of demand calculated patient demand by reference to patient consumption as expressed in responses to the patient survey. The Freedman report calculated the estimated demand for each class of cannabis flower and products based on data that current qualified patients reported in the survey, and also calculated the equivalent amount of cannabis in pounds required to produce cannabis-derived products. By this calculation, the report found that 13,858.22 pounds of cannabis would be required for a three-month period to meet demand. Applying a national average of .75 pounds of cannabis harvested per plant, the report found that demand could be met with 18,477.63 plants over a three-month period. That figure, divided by the current 34 licensed nonprofit producers, would require a plant limit of **543.46 plants** per producer, assuming that each producer harvests on average a quantity of cannabis equal to their maximum plant count four times per year (a figure based on national standards and validated by the producer survey).

The second measure of demand identified in the Freedman report was based on a methodology offered by Kelly O’Donnell, an industry representative affiliated with the licensed nonprofit producer New Mexico Top Organics - Ultra Health. That calculation multiplied the number of enrolled patients by the absolute maximum quantity that patients can possess in a three-month period,¹ and subtracted the quantity yielded by personal production license holders. That calculation resulted in a patient demand figure of 32,884 pounds per quarter, which (again assuming 4 harvest cycles per year and an average yield of .75 pounds per plant) required a plant limit of **1,289 plants** for each of the current 34 licensed nonprofit producers.

The third measure of demand identified in the report was based on a methodology proposed by another industry representative, Reynold Greenleaf and Associates (a licensed nonprofit producer). Applying this method resulted in a calculated demand of 44,677 pounds per quarter, which would require **1,752 plants** per producer, assuming an average yield of .75 pounds per plant.²

The last measure of demand that was cited in the Freedman report multiplied the total number of actively enrolled patients by the absolute maximum quantity of cannabis that a qualified patient could possess

¹ As noted above, this figure far exceeds the quantity of cannabis that is actually consumed by qualified patients as identified in the patient survey, and is for that reason a less realistic measure of demand.

² In its calculation, the R. Greenleaf report assumed a yield of 0.875 pounds per plant, which the Freedman report replaced with the more conservative .75 pounds-per-plant national average that was used in the other calculations.

under the adequate supply use and possession limit, including the equivalent amount of cannabis in pounds required to produce cannabis-derived products, and did not factor for amounts produced by personal production license holders. This calculation measured demand as 36,188 pounds per quarter, which would require **1,419 plants** per producer (again, assuming that producers harvest all of their plants 4 times per year).

In its proposed rule, the Department has proposed to increase the plant limit from the previous limit of 450 plants per producer, to 1,750 plants per producer. This figure meets or exceeds the totals suggested by the industry models presented (using a conservative estimate of yield-per-plant, and a conservative harvest standard that assumes only quarterly harvests), and far exceeds the plant limit of 543 per producer that was determined necessary to meet actual demand based on the patient survey.

The proposed rule also incorporates mechanisms by which licensed nonprofit producers can request increases to their plant limits, based in part on demand experienced by the producer. Starting in June of 2021, licensed nonprofit producers would be able to request an increase to their plant limit, to increase their limit by 500 plants in a renewal cycle and by 500 additional plants on an emergency basis. Such increases would require that the licensed nonprofit producer demonstrate the need, and the requests would be granted solely within the Department's discretion.

The proposed plant limit is based on conservative estimates of yields and harvests. The proposed plant limit does not factor other actions that could be taken outside of rulemaking to increase the availability of cannabis in the Medical Cannabis Program, including licensing of additional nonprofit producers beyond the current total of 34. The proposed plant limit does not factor anticipated increases in production resulting from improved growing methods and other effects of improved economies of scale. The proposed plant limit also does not factor the beneficial impact that licensed nonprofit producers will experience as a result of seedlings (defined as cannabis plants without flowers that are less than 8 inches in height) no longer being counted against the plant limit for licensed nonprofit producers. This change will effectively allow producers to possess an even greater number of plants than the limit permits. Pursuant to changes adopted to the Lynn and Erin Compassionate Use Act under Senate Bill 406 from the 2019 legislative session, patients (including personal production license holders) are now able to gift cannabis to one another, and this is anticipated to increase availability of supply to patients, although this was also not factored in the proposed limit.

The proposed plant limit rule is calculated to meet and exceed actual demand within the Medical Cannabis Program, and ensures the ability of the Department to expand plant limits as necessary to meet future demand. The proposed rule is supported by reference to actual data from patient and producer surveys, as well as industry projections. By limiting the number of plants in the Program, the Department intends to limit the potential for over-production of cannabis, which would contribute to greater potential for diversion of cannabis.

(A)(2): Removal of an existing prohibition against volume discounts and promotional sales by licensed nonprofit producers: This amendment is primarily proposed in response to past public comments requesting its removal.

(M): Removal of 70% THC limit: the THC concentration limit is removed to reflect statutory amendments from SB406.

Addition of video-taped destruction of usable cannabis by licensed non-profit producer: the Department added this requirement to ensure that non-profit producers' destruction of usable cannabis is appropriately documented, and to ensure that the video is made available to the Department upon request.

(Q): Licensure period for non-profit producers during transition to 2019 rules: the licensure period for non-profit producers for the period that would otherwise end on August 1, 2019 is extended until September 30, 2019, in recognition of the proposed rule changes to plant limit and licensing fees, and in recognition of the fact that the anticipated rules will not take effect until sometime after August 1, 2019.

(S)(3): \$50 fee for replacement of personal production license card deleted and removed to 7.34.4.17(W)(5) NMAC, below. This amendment is proposed for purposes of clarification. This passage concerns application requirements generally, rather than replacement cards, and so the charge for replacement of a PPL card was moved to another section that concerns replacement license fees.

(W)(2): Licensure fees for non-profit producers: previous tiered fee structure is modified, in part to address proposed change to the number of plants that non-profit producers can possess. The previous licensure fees were 1) \$30,000 for the first 150 plants (which included seedlings); 2) \$10,000 for each additional increment of 50 plants, up to 450. The proposed licensure fees are 1) \$40,000 for the first 500 plants; 2) \$5,000 for each additional increment of 50 plants up to 1,000 plants; and 3) \$6,000 for each additional increment of 50 plants over 1,000 plants.

A non-profit producer that chooses to grow 500 plants at a time would pay \$40,000 per licensure year (\$80 per plant, versus \$200 per plant under the existing rule). A non-profit producer that grows 1,000 plants at a time would pay \$90,000 per licensure year (\$90 per plant). A non-profit producer that grows up to the proposed limit of 1,750 plants at a time would pay \$180,000 per licensure year (approx. \$103 per plant). As noted, these plant limits do not include seedlings.

The Medical Cannabis Program is not funded through state General Fund monies, but is funded primarily by nonprofit producer licensing fees. The Department assesses substantially higher fees to licensed nonprofit producers than other licensees, in recognition of the fact that nonprofit producers make substantially greater revenue than other licensees and have much larger budgets, and in recognition of the fact that nonprofit producers control the production and sale of cannabis within the Program and are therefore in a superior position to bear the expense and build it into their retail prices. Fees for licensed nonprofit producers are also greater in consideration of the fact that, among the commercial licensees in the Program, licensed nonprofit producers require a significantly greater expenditure of administrative resources to regulate. While it is difficult to anticipate with certainty either the revenue to be received as a result of the proposed fees, or the costs of the Medical Cannabis Program, the Program anticipates that there may be added revenue from the proposed fee changes, and also anticipates that the Program will incur additional expenses related to the hiring of additional full-time employees, various software improvements, and other costs beyond the Program's current budget.

(W)(3): Submittal period for annual renewal license fee extended for 2019 from July 1 to August 1, 2019, to September 1, 2019 to October 4, 2019. Like the licensure period extension described above, this amendment is proposed in recognition of the fact that the proposed rules will not become effective until sometime after August 1, 2019. The 2019 renewal licensure fees are not proposed to be prorated to reflect the decreased licensure period. This is due to the fact that non-profit producers will also have benefitted from the expansion of the 2018-2019 licensure period to September 30, 2019, during which period the old fees (capped at \$90,000) are applied to the 2,500 plant limit of the emergency rule of 3/1/19.

(W)(4): Replacement license fee of \$50 for PPL moved. As noted above, the \$50 fee for replacement of a PPL license card was moved to this subsection, which concerns replacement licensure fees rather than application fees.

7.34.4.9 NMAC:

(A): Added reference to ability of either qualified patient or primary caregiver to hold a personal production license to grow cannabis for the qualified patient's use. This amendment is proposed to reflect statutory changes adopted in SB406. See NMSA 1978, § 26-2B-3(R).

(B): Removed requirement that personal production license holder's location for growing medical cannabis plants be either the patient's primary residence or other property owned by the qualified patient. This amendment is proposed to allow personal production license holders to grow cannabis at locations other than their home or property they own. It is also made in recognition of the ability (established under SB406) of a primary caregiver to hold a personal production license to grow cannabis on behalf of a qualified patient. See NMSA 1978, § 26-2B-3(R).

7.34.4.19(B) NMAC: Replacement of reference to "mature female plants, seedlings, and male plants" with "cannabis plants". This amendment is proposed for the purpose of simplification, and to remove the reference to seedlings being counted against a non-profit producer's plant limit. As noted, under the proposed rule amendments, seedlings will no longer be counted against a non-profit producer's plant limit.

7.34.4.23 NMAC:

(B)(1): Inclusion of statement, "including data from point of sale systems", and reference to inspection and copying, in passage concerning financial records. These amendments are proposed to clarify the Department's ability to access, inspect and copy financial records of licensed non-profit producers, including but not limited to data from point of sale systems.

(B)(3): Identification of information to be included in quarterly reports from licensed non-profit producers. This amendment is proposed to identify information that the Department requires to be included by licensed non-profit producers in those producers' quarterly reports to the Department.

7.34.4.24 NMAC:

(A): Removal of current provisions regarding disciplinary actions that may be taken by NMDOH against non-profit producers, manufacturers, laboratories, and couriers, and applicants for those licensing designations. These amendments would primarily replace current provisions regarding disciplinary actions, adopting in their place a tiered structure that classifies licensee violations in terms of severity, consisting of 1) major violations implicating public safety, 2) major violations not implicating public safety, and 3) other violations. These include items from the existing rule and additional items. The amendments to this section are proposed in part on the basis of suggestions that were made by the consulting company Freedman & Koski in its report to the Department.

(B): Amendments to fines. The fines in the existing rule are proposed to be amended, to enable more substantial monetary penalties for the violations identified above. These amendments are proposed in part on the basis of suggestions that were made by the consulting company Freedman & Koski in its report to the Department. The proposed fines are 1) up to \$50,000 for each major violation implicating public safety, 2) up to \$20,000 for each major violation not implicating public safety, and 3) up to \$5,000 for each other violation. The Department is proposing these increases to potential fines in order to increase its ability to sanction licensed entities for noncompliance with Department rules and other violations. The Department is concerned that the current fine structure of \$100/\$500/\$1,000 per violation is not significant enough to encourage regulatory compliance, and discourage regulatory noncompliance, by licensees.

7.34.4.25(C) NMAC: Exemption from state criminal and civil penalties for public schools and school districts, *et al.*, and designated school personnel. This additional text is proposed to be added to the rule in recognition of statutory amendments adopted in SB406. See NMSA 1978, § 26-2B-5(A). SB406 includes various amendments to the Public School Code that allow the use of medical cannabis within public school settings by enrolled students, and that will enable designated school personnel to possess and store those products in school settings and administer those products in school settings to students who are qualified patients. By this amendment, the Department will recognize the public schools, school districts, *et al.* as licensees as that term is used at NMSA 1978, § 26-2B-4(G), who are therefore entitled to immunity from prosecution or civil penalty for activities conducted within their licensure and in accordance with the Public School Code.

This amendment is proposed to further the purposes of the statutory amendments, and specifically to enable the administration of cannabis to qualified students in public school settings, consistent with applicable state laws. Note, however, that the Department of Health does not hold authority with respect to the creation of rules regarding the administration of cannabis in school settings. Pursuant to the amendments to the Public School Code identified in SB406, that rulemaking authority is held by the NM Public Education Department, which is currently in the process of promulgating rules on the subject.