

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.

7.34.3 NMAC:

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

7.34.4 NMAC:

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

“Approved laboratory”: struck in favor of adding definition for “laboratory” that references statutory definition of “licensed cannabis testing facility”, which was added to statute by SB406 (2019). See NMSA 1978, § 26-2B-3.

“Approved entity”: definition added to distinguish manufacturers, laboratories, and couriers from licensed producers. All of these entities are licensed by NMDOH, but references in the rules to “licenses” generally refer to producer licenses.

“Cannabis consumption area”: new definition added based on statutory definition, which was added to statute by SB406 (2019). See NMSA 1978, § 26-2B-3.

“CBD”; “CBDA”: new definitions added.

“Courier”: existing definition amended to cross-reference the statutory definition of “cannabis courier”, which was added to statute by SB406 (2019). See NMSA 1978, § 26-2B-3.

“Diversion”: new definition added.

“Dried usable cannabis”: new definition added.

“Inversion”: new definition added.

“Laboratory”: new definition added to cross-reference statutory definition of “cannabis testing facility”, which was added to statute by SB406 (2019). See NMSA 1978, § 26-2B-3.

“License”; “Licensure”: previous definitions referencing only producers removed in recognition that “approved entities” are effectively licensed by NMDOH, as expressed in statutory amendments to NMSA 1978, § 26-2B-3 from SB406 (2019) that identified “cannabis couriers”, “cannabis manufacturers”, and “cannabis testing facilities” as persons “licensed” by the Department.

“Manufacturer”: existing definition amended to cross-reference statutory definition of “cannabis manufacturer”, which was added to statute by SB406 (2019). See NMSA 1978, § 26-2B-3.

“Pesticide”: new definition added to cross-reference pesticide as defined by the New Mexico Pesticide Control Act, NMSA 1978, § 76-4-3 *et seq.*

“Reciprocal limit”: new definition added to reflect amendments to statute made by SB406 (2019), which established reciprocity, and which require that the quantity of cannabis possessed by a “reciprocal participant” not exceed “the limit identified by department rule”. See NMSA 1978, § 26-2B-4(B), (C).

“Reciprocal participant”: new definition added based on statutory definition, which was added to statute by SB406 (2019). See NMSA 1978, § 26-2B-3.

“THCA”: new definition added.

“Testing”: existing definition amended for clarification.

“Wastage”: new definition added.

7.34.4.8 NMAC:

(D)(3): “A non-profit producer” replaced with “[a]n applicant” in recognition that this passage concerns applicants whose applications are not yet approved.

(I): Reference to “qualified patients” removed to clarify that a qualified patient is not ordinarily subject to criminal history screening under NMDOH rule. A qualified patient who is an employee, contractor, or board member, etc., of a non-profit producer, manufacturer, courier, or laboratory, will however be subject to criminal history screening in that capacity.

(K): Existing text struck to remove old reference to 150 plants, and to allow licensed non-profit producers (LNPPs) to request an additional production facility, to be granted or denied at the Department’s discretion, irrespective of the number of plants that the producer is approved to grow.

(M): Amended to specify that destruction of both cannabis and cannabis plants must be documented in accordance with the rule.

(O)(13): Added requirement that producer submit attestation that it will prohibit its employees and contractors from being under the influence of drugs or alcohol in the workplace.

(P): Struck requirements for tender of employee training documentation to the Department. Department access to materials is specified elsewhere in the rule, including the section regarding monitoring (currently 7.34.4.23 NMAC).

(Q)(2): Clarified existing text regarding the licensure period for personal production licenses.

(Q)(3): Included requirement that LNPP employees carry their Department-issued employee i.d. card at all times during their work and present the card to law enforcement upon request.

(R)(3): Added reference to an LNPP manufacturing plan.

(U): Struck existing text regarding closure of LNPP operations, which is proposed to be replaced by a new rule section 7.34.4.32 NMAC, “Closure of a Non-Profit Producer or an Approved Entity.”

(V): Specified that the LNPP license must be maintained at both production locations and dispensary locations.

(W)(4): Specified that a licensure fee that is paid by a newly-licensed LNPP for initial licensure will be pro-rated based on the amount of time that remains in the licensure period.

(Y): Added theft and break-in notification requirement for LNPPs.

(Z): Added provision to clarify that the applications period for LNPP licensure may be opened and closed by the Department, and included similar text in sections regarding manufacturers, laboratories, and couriers.

7.34.4.9 NMAC: This is a proposed new section that identifies minimum standards (primarily, hygiene standards) for the production of cannabis by a licensed non-profit producer. The requirements largely duplicate existing requirements that apply to the manufacture of cannabis-derived products.

7.34.4.10 NMAC: The Department has proposed various revisions and additions to the requirements for testing of dried usable cannabis and cannabis-derived products. The proposed testing standards include new tables that specify action levels for microbiological, mycotoxin, residual solvent testing. New testing requirements are proposed for testing for the presence of heavy metals, certain pesticides, and moisture content. The rule specifies minimum sample sizes for the various required tests, and includes revised remediation standards for dried usable cannabis and cannabis-derived products. The rule also proposes to require random weekly testing of finished cannabis derived products, including edible products. The proposed rule also expands the scope of potency testing, to include certain additional cannabinoids, and would require that a cannabis-derived product be homogenous in composition with respect to THC potency.

The microbiological testing requirements are based on section 2023 of the United State Pharmacopeia, which is also referenced in the current version of the rule.

The mycotoxin testing requirements are consistent with past guidance provided by the Department to LNPPs, manufacturers, and laboratories.

Residual solvent testing requirements are also consistent with past guidance provided by the Department to LNPPs, manufacturers, and laboratories. The residual solvent standards are based in part on standards adopted in Oregon, and were also created in consideration of discussions between NMDOH personnel and commercial laboratory operators in Colorado.

Potency testing requirements are, with respect to mandatory reporting, essentially unchanged from current requirements. The rule does include certain additional cannabinoids for which testing is optional.

Heavy metals testing requirements are newly created. These are based in part on a review of standards in other states, including California, Washington, Nevada, and Oregon.

Pesticide testing requirements are also a new addition to the rule. The listed pesticides were selected partly with reference to Colorado's regulations. The identified action levels are borrowed primarily from regulations of the Oregon Health Authority.

The minimum test sample sizes are based on the United States Pharmacopeia standards for dried botanicals and botanical extracts.

The remediation standards at the proposed 7.34.4.10(F) NMAC allow remediation of dried usable cannabis and cannabis derived products when dried cannabis has failed a microbiological test, and when cannabis derived product has failed a microbiological test or residual solvent test. An LNPP or manufacturer may not remediate cannabis or cannabis derived products that fail other tests required by the rule. The Department is not aware of a reliable, safe method to remediate dried usable cannabis for mycotoxins, solvent residue, heavy metals, or pesticides. Upon information and belief, other states, including Colorado, have prohibited remediation of cannabis for the same reason.

7.34.4.11 NMAC: This is a new section that proposes to include requirements specific to the "wastage" (i.e., destruction) of usable cannabis and cannabis plants by an LNPP or an approved entity. It includes permitted methods of wastage and disposal, a holding period for cannabis and cannabis plants intended to be wasted, and documentation and notice requirements.

7.34.4.12 NMAC: The Department has proposed to add provisions for quality assurance testing of usable cannabis, to be conducted by the Department.

7.34.4.13 NMAC: This section includes a proposed revision to require that pesticides be stored in a secured area, and that pesticides be segregated from usable cannabis, cannabis plants, and products and equipment that are used in the manufacturing or production process. This is intended to avoid issues with contamination.

7.34.4.14 NMAC:

(A): The application requirements for manufacturers are proposed to be amended to increase the licensing application fee for manufacturers, from the current \$1,000 to \$5,000. The Department believes that this fee increase is appropriate in light of the size and the revenues of licensed manufacturers, and given the expanded abilities of manufacturers under the statutory amendments that were made via SB406 (2019). While the proposed \$5,000 fee is substantially less than the fees paid by licensed non-profit producers, the Department finds that LNPPs and manufacturers are not comparable, considering that LNPPs have much higher revenues than manufacturers, and given that LNPPs, as the only entities permitted to sell cannabis or cannabis products to the public, control the market and the prices for cannabis products in a way that no one else does.

(B)(3): This provision would require hazard analysis critical control point plans (HACCP plans) for each of the products that a manufacturer applicant intends to manufacture. HACCP plans are plans that address

the safety of products to be consumed, through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product.

(4): Application requirements amended to include a detailed list of all products to be manufactured.

(8): Application requirements amended to include requirement that manufacturer applicants submit proof that no buildings to be used by the manufacturer are located within 300 feet of a school, church, or daycare center. This 300-foot requirement is based on a requirement of the statute, at NMSA 1978, § 26-2B-7.

(13): Application requirements for manufacturers amended to include submittal of documentation of successful testing of alarms and a law enforcement notification system.

(18) Added requirement that manufacturer applicant submit attestation that it will ensure that all persons who work at its facilities be 18 years of age or older. This is intended to limit access of minors to cannabis.

(19)-(24): Propose various additional application submittal requirements identified for manufacturer applicants. These include, at (22), submittal of an attestation that the applicant will comply with all applicable state and local zoning, occupancy, licensing, and building codes; and, at (23), proof of prior approval from the NM Regulation and Licensing Department for the use of compressed gas extraction equipment.

(C): This proposes to include new material in the rule that prohibits certain additives, including polyethylene glycol, polypropylene glycol, vitamin E acetate, and medium chain triglycerides, in products that are intended to be consumed by inhalation, such as vaping cartridges. This relates to a recent outbreak of severe lung injuries sustained by individuals across the country from vaping cannabis and/or nicotine products. Although the cause of these injuries is not yet known, there have been indications that the identified additives may be the source, and various states have taken measures to limit the presence of these substances in vaping products. For more information regarding vaping-related lung disease, see the Department of Health's website at <http://nmhealth.org/about/erd/eheb/vri/> and the CDC website at <http://www.cdc.gov/lunginjury>

This passage also proposes to prohibit manufacturers and non-profit producers from adding nicotine, caffeine, or any other addictive substance to a cannabis product.

(E): Proposes additional requirement for manufacturer employees to carry their Department-issued employee i.d. card at all times during their work.

(F): Proposes additional requirement that a manufacturer that intends to change locations, board directors, methods of manufacturing, etc., or that intends to change its security plan, first seek amendment to their licensure.

(G): Proposes to require manufacturers to use equipment, software, and services that are specified by the Department for tracking inventory, sales, and other information, and for reporting that information to NMDOH. This is modeled after a similar, existing requirement that applies to LNPPs.

(H): Theft and break-in reporting requirement. This is identical to the theft and break-in reporting requirement that is proposed to apply to LNPPs, mentioned above.

(I): Closure of applications period. This is similar to the requirement for LNPP applications periods, described above.

7.34.4.15 NMAC:

(A): Proposed revisions to the general manufacturing requirements for LNPPs and manufacturers include various additional items, including requirements that manufacturing be conducted in a manner that does not allow cross-contamination from chemical or biological hazards; that manufacturing not occur within 300 feet of a school, church, or daycare center (consistent with the statutory 300-foot requirement described above); that persons involved in handling cannabis and cannabis derived products wash their hands before putting on gloves and after removing gloves; that walls and ceilings remain free of water damage, and that insulation not be exposed; that chemicals used in extractions be intended for such usage and be of food or medical grade; that weighing devices be registered and calibrated in accordance with requirements of the Department of Agriculture; that any manufacture of cannabis derived product for a PPL holder be recorded in an electronic tracking system specified by the Department; and that employees not be under the influence of drugs or alcohol in the workplace.

(B): Proposed revision to existing rule, to state that DMSO cannot be possessed on the premises of an LNPP. Federal law restricts the use of DMSO.

7.34.4.16 NMAC:

(A): Proposed rule would prohibit packages that contain usable cannabis from displaying content that reasonably appears to target minors (such as cartoon characters), and would prohibit product names and packages from being modeled after a brand of product that is traditionally marketed toward children. This is intended to keep cannabis packaging from being enticing to children, who may mistake a cannabis product for candy or some other ordinary food product.

(B); Table 8: The proposed rule would require that cannabis products be labeled using a standardized label format, shown in Table 8. The label includes various information regarding the contents of a package, as well as laboratory analysis results. The label would also include certain warnings, including the warning regarding the vaping of THC that was included via a recent emergency rulemaking, described below.

(C), Table 9: The proposed rule would also require that drug information sheets be provided to qualified patients and primary caregivers at the time a cannabis product is sold or distributed to them. The drug information sheet would contain all of the information contained in the package label, as well as certain additional information, such as information regarding any pesticides used in the product's production or manufacture.

(D): New proposed provision would prohibit removing or obscuring an expiration date, and would require that products whose expiration dates have passed be wasted in accordance with the terms of the rule.

(E): This provision contains a requirement that cannabis derived products that contain THC and that are intended to be consumed by vaporization (vaping) have a warning affixed which states in bolded text, “WARNING: Vaping THC has been associated with cases of severe lung injury, leading to difficulty breathing, hospitalization, and even death.” This requirement was first instituted by a public health order of the Department and an emergency rule that took effect on October 4, 2019. The warning was required in consideration of the recent outbreak of severe lung injuries stemming from vaping of THC and nicotine products, described above in regard to 7.34.4.14(C) NMAC.

(F): This provision identifies that a non-profit producer that does not comply with the packaging or labeling requirements of the rule can see their sales and distribution of non-compliant products suspended and may be subject to discipline against their licensure.

7.34.4.17 NMAC:

(C): Laboratory application materials requirements are proposed to be amended to include documented proof of initial demonstrations of capability (in accord with the rule); proof that buildings are not located within 300 feet of a school, church, or daycare center, and an attestation of the same.

(G): Included requirement that laboratory employees carry their Department-issued employee i.d. card at all times during their work and present the card to law enforcement upon request.

(H): Included theft and break-in reporting requirement.

(J): Proposes additional requirement that a laboratory that intends to change locations, that intends to make a physical modification or addition to its facilities (new testing equipment, etc.), or that intends to make a substantial change to its standards operating procedures or types of tests to be conducted, first seek amendment to their licensure.

7.34.4.18 NMAC:

(A): Requires that laboratories apply the testing standards contained elsewhere in the rule to determine whether a sample of usable cannabis passes a given test.

(C): Clarifies that a laboratory that receives a usable cannabis sample for testing must record the batch number or code that is recorded by an LNPP or manufacturer in an electronic tracking system specified by the Department. This is intended to more clearly associate test samples with the batches from which they are derived.

(E): Requires that laboratories comply with all state and federal laws, including but not limited to zoning, occupancy, licensing, and building codes.

(K)(2): Includes certain requirements regarding the recording of analytical data, including requirements for making changes to recorded data.

(Q): Includes requirement that laboratory employees and contractors not be under the influence of drugs or alcohol in the workplace.

(R): Includes provision stating that repeated failures to comply with testing requirements may result in disciplinary action against a laboratory.

7.34.4.19 NMAC: This is a proposed new section of the rule that identifies instrumentation requirements for the various tests to be conducted under Department rule. These instrumentation requirements are proposed to ensure that the testing instrumentation that is utilized for the various tests can accurately measure for the concentrations of contaminants that are specified.

The permitted instrumentation for testing do not include enzyme-linked immunosorbent assay (ELISA) instrumentation. Upon information and belief, and based on a review of scientific literature, ELISA is only accurate in testing for one type of mycotoxin tested under the rule (aflatoxin B1); and ELISA tends to undermeasure for the other three mycotoxins. Furthermore, ELISA tends to over-measure for ochratoxin B and ochratoxin C, which can then be reported as a false positive for ochratoxin A. ELISA is notorious for reporting false negatives and false positives. The preferred method for mycotoxin testing is LCMS. Of note: when using LCMS, the mycotoxin and pesticide tests can typically be combined into one analysis, such that costs of testing can be reduced. In contrast, ELISA testing typically costs in the range of \$400 per plate.

This proposed section also includes, at (F), that laboratories and laboratory applicants submit to the Department an initial demonstration of capability (IDC) for each type of test that the laboratory intends to conduct. The IDCs include demonstrations of method calibration, method accuracy, method detection, low system background, and analyte detection. The purpose of the IDC requirements is to ensure that a laboratory or laboratory applicant is capable of conducting the tests that they intend to conduct, and that the method that is utilized returns accurate results.

7.34.4.20 NMAC:

(B)(15): Corrected faulty reference to “non-profit producer” in the couriers section, to refer instead to “applicant”.

(B)(24) Required attestation that courier will not transport cannabis across state lines. The transport of cannabis across state lines violates both state and federal law.

(C): Identified \$1,500 application fee for courier applicants.

(D)(12): Added requirement that couriers, when transporting cannabis, not utilize vehicles that indicate that the vehicle is used for the transport of cannabis. This could, for example, include a courier name or logo, if the courier is exclusively or primarily engaged in the transport of cannabis. This is intended as a safety precaution for patients and for courier employees.

(G): Proposes additional requirement that a courier that intends to change locations, board directors, courier facilities, etc., or that intends to make a substantial change to the courier’s methods of storage, transport or delivery, submit an application for amended licensure.

(H): Added theft and break-in reporting requirement.

(I): Added prohibition against courier employees being under the influence of drugs or alcohol in the workplace.

(J): Added provision that the Department can require a courier to use certain equipment, software, and services to track distribution, inventory, and other information, and for the purpose of reporting information to the Department.

7.34.4.22 NMAC:

(B)(5): Included exception in LNPP attestation requirement regarding patients not consuming cannabis on the LNPP's premises. This is made in recognition of the recent additions to statute regarding cannabis consumption areas, which are addressed in the proposed section 26 of the rule (see below).

(C)(1): Includes premises to be used in manufacturing within the description of facilities portion of the LNPP application rules. LNPPs are permitted within their licensure to manufacture cannabis derived products in accordance with applicable Department rule.

(L): Revised existing reference to "local ordinances" to clarify that LNPPs must comply with both state and local laws regarding construction, occupancy, and operation of a facility or building, including zoning requirements, etc.

7.34.4.26 NMAC: This is a new section that identifies the application and operational requirements for cannabis consumption areas. SB406 (2019) amended the statute to create cannabis consumption areas that are occupied on licensed premises in accordance with NMDOH rules. The Department has proposed to allow cannabis consumption areas to be operated at licensed nonprofit producers' approved dispensary locations. Pursuant to statute at NMSA 1978, § 26-2B-6.1, access to cannabis consumption areas must be restricted to qualified patients and their primary caregivers; cannabis consumption cannot be visible from any public place or from outside the cannabis consumption area; and qualified patients who consume cannabis on the premises must have a designated driver or other means of transportation consistent with applicable law (a patient cannot drive a motor vehicle from a cannabis consumption area while under the influence of cannabis).

7.34.4.27 NMAC: This is a new section that identifies standards for reciprocity for individuals who hold proof of authorization to participate in the medical cannabis program of another state, territory, or commonwealth of the United States, or a New Mexico Indian nation, tribe, or pueblo. This was also added to statute via SB406 (2019), at NMSA 1978, § 26-2B-7. The proposed reciprocity standards would permit reciprocal participants to purchase cannabis products from licensed non-profit producers using the medical cannabis i.d. card or other proof of authorization obtained from their home state or territory. The rule proposes a reciprocal limit for possession of cannabis and cannabis products, which is identical to the 230-unit "adequate supply" limit that applies to enrolled qualified patients. Reciprocal participants must be registered by an LNPP, and sales and transfer to reciprocal participants must be tracked in the electronic tracking system specified by the Department. LNPPs are required to provide informational materials to reciprocal participants at the time of the sale or transfer, which identify the

possession limit, as well as a notice concerning prohibitions against interstate transfer of cannabis under state and federal law.

7.34.4.28 NMAC: This section includes provisions for enforcement of the NM Parental Responsibility Act, NMSA 40-5A-1 *et seq.*, which applies to persons who apply for or hold a license, certificate, registration or permit that is issued by a licensing board or other authority that issues licenses, certificates, registrations, or permits to engage in a profession or occupation regulated in New Mexico. The Department of Health’s Medical Cannabis Program fits within that description, insofar as it permits persons to work for licensed non-profit producers and approved entities. Such persons may be prohibited from working for the LNPP or approved entity if they are not in compliance with a judgment and order for child support that was issued by a district court or tribal court, or if they are not in compliance with a subpoena or warrant relating to paternity or child support proceedings.

7.34.4.29 NMAC:

(B)(3)(r): An existing requirement that LNPPs include a detailed description of thefts, robberies, and break-ins in their quarterly reports is proposed to be removed, in favor of the theft and break-in provision that has been proposed to be added at 7.34.4.8(Y) NMAC.

(C): Corrective action subsection is proposed to be amended to identify that violations that are cited on the basis of violations that are directly observed in the course of a monitoring visit, the LNPP will receive a written report of findings within 7 days, and will be afforded the opportunity to correct the violations within five days. This is to clarify that if, for example, the Department learns of a violation that is occurring off-site, the seven-day report provision and the five-day corrective action provision will not apply.

7.34.4.30 NMAC:

(A): Disciplinary actions section is proposed to be amended to include a statement that a notice will be deemed to be served on the date of delivery that is shown on the return receipt of the certified U.S. postal mail, or on the last attempted delivery date. This is patterned after a similar standard that applies in the context of cases that fall within the Uniform Licensing Act. *See* NMSA 1978, § 61-1-5.

(B): Subsection concerning grounds for disciplinary action includes proposed amendments to state that disciplinary actions described therein are not exclusive of one another, and can be imposed in any combination.

(1)(b): Major violations of public safety are amended to include “inversion”, or attempted diversion or inversion. Inversion is a term, defined in the proposed rule, that refers to the unlawful acquisition of a cannabis plant, plant material, or cannabis-derived product; whereas diversion refers to the unlawful transfer of the same.

(E): New provision states that a hearing cannot be requested solely on the basis that an applications period is closed.

(F): Passage regarding timing and content of requests for hearing include clarifying text regarding the timeline for responding to a notice of contemplated action versus responding to a notice of immediate action. This also includes a requirement that requests for hearing must be mailed via certified mail. This is intended to ensure that, in the event that a request for hearing becomes lost in the mail, the requestor has proof that the request was in fact sent on a given date within the specified periods.

7.34.4.32 NMAC: New section proposes to establish closure requirements for LNPPs and approved entities. This text borrows from and adds to existing closure requirements in the rule.