

NMAC

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2019 AUG 15 PM 4: 29

Volume: Issue: Publication date: Number of pages: (ALD Use Only) Sequence No.

Issuing agency name and address: Agency DFA code:

Contact person's name: Phone number: E-mail address:

Type of rule action: (ALD Use Only) Most recent filing date:
New Amendment Repeal Emergency Renumber

Title number: Title name:

Chapter number: Chapter name:

Part number: Part name:

Amendment description (If filing an amendment):
Amendment's NMAC citation (If filing an amendment):

Are there any materials incorporated by reference? Yes No
Please list attachments or Internet sites if applicable.

If materials are attached, has copyright permission been received? Yes No Public domain

Specific statutory or other authority authorizing rulemaking:

This rulemaking is made in accordance with the following authorities: Section 9-7-6, NMSA 1978; Section 26-2B-7, NMSA 1978 and Section 24-1-3, NMSA 1978.

Notice date(s): Hearing date(s): Rule adoption date: Rule effective date:

Concise Explanatory Statement For Rulemaking Adoption:

2019 AUG 15 PM 4: 29

Findings required for rulemaking adoption:

Findings MUST include:

- Reasons for adopting rule, including any findings otherwise required by law of the agency, and a summary of any independent analysis done by the agency;
- Reasons for any change between the published proposed rule and the final rule; and
- Reasons for not accepting substantive arguments made through public comment.

The amendments include but are not limited to modifications to provisions concerning: the plant limit for licensed nonprofit producers, fees for licensed nonprofit producers, disciplinary actions against licensees, and the definition of "seedling"; as well as inclusion of a definition for "nonprofit producer and a provision to allow LNPPs to possess unlimited numbers of seedlings, and removal of references to a THC limit for cannabis derived products.

The reasons for adoption of these amendments are as stated in the attached Statement of Reasons dated August 12, 2019, by which the Cabinet Secretary, Kathyleen M. Kunkel, adopted the rule amendments, and which is hereby incorporated by reference. The reasons for adoption are further expressed in the rulemaking record that is held by the NM Department of Health, which includes but is not limited to the Report and Recommendation of the Hearing Officer, Craig T. Erickson, Esq., dated 8/7/19, Exhibits 1 through 17, the audio recording of the rule hearing conducted on 7/12/19, and correspondence between the Department of Health and the Hearing Officer regarding public comments received by the Department.

Issuing authority (If delegated, authority letter must be on file with ALD):

Name:

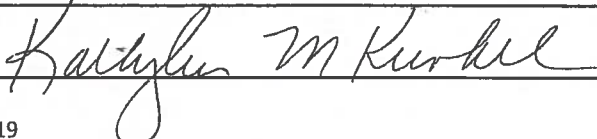
Kathyleen Kunkel

Check if authority has been delegated

Title:

Cabinet Secretary

Signature: (BLACK ink only)



Date signed:

8/15/19

STATE OF NEW MEXICO 2019 AUG 15 PM 4: 29
BEFORE THE SECRETARY OF HEALTH

**IN THE MATTER OF PROPOSED
AMENDMENTS TO RULES
7.34.2, 7.34.3 AND 7.34.4 NMAC**

**STATEMENT OF REASONS
FOR ADOPTION OF RULE AMENDMENTS**

The Cabinet Secretary for the New Mexico Department of Health (“Department”), Kathyleen M. Kunkel, hereby adopts proposed amendments to Medical Cannabis Program rules at 7.34.2 NMAC at sections 7, 8 and 10, 7.34.3 NMAC at sections 7, 8, 9, 10, 11, 15, 17, and 19, and 7.34.4 NMAC at sections 7, 8, 18, 19, 23, 24, and 25, as partly revised in response to public comments, and in consideration of the recommendations submitted by the Hearing Officer, Craig T. Erickson, Esq. following a public hearing conducted on July 12, 2019. This decision is based on the entire record in this matter, which includes Exhibits 1 through 17, the audio recording of the hearing, written correspondence between the Department and the Hearing Officer, and the Report and Recommendation of the Hearing Officer, Craig Erickson, Esq., dated August 7, 2019 and received by the Cabinet Secretary on August 9, 2019 via U.S. postal mail.

In further support of this action, the Cabinet Secretary finds the following:

1. The Department of Health is authorized to promulgate rules as may be necessary to carry out the duties of the Department and its divisions. NMSA 1978, § 9-7-6(E).
2. The Department is also authorized to promulgate rules to implement the purpose of the Lynn and Erin Compassionate Use Act. NMSA 1978, § 26-2B-7.
3. In accordance with NMSA 1978, Section 9-7-6(E) and NMSA 1978, § 14-4-5.2, notice of the July 12, 2019 hearing for the proposed rule amendments was provided to the public,

which included publication in the Albuquerque Journal newspaper on June 11, 2019, and publication in the New Mexico Register on June 11, 2019.

4. By a letter dated May 31, 2019, the Cabinet Secretary designated Mr. Erickson to serve as Hearing Officer for the purpose of conducting the hearing, receiving and reviewing public comment, and submitting a recommendation regarding the proposed rule amendments.

5. A public rule hearing was held in Santa Fe, New Mexico, on July 12, 2019 in accordance with NMSA 1978, Section 9-7-6(E).

6. Members of the public were afforded the opportunity to submit data, views and arguments on the proposed rules orally and in writing, and those comments were received by the Hearing Officer until the close of the public hearing on July 12, 2019.

7. The purpose of the proposed rule amendments is to adopt various revisions to 7.34.2 NMAC, 7.34.3 NMAC, and 7.34.4 NMAC, as more fully described in the rulemaking record, which revisions include but are not limited to the following:

- Modifications to the definition sections of all of the Medical Cannabis Program rules (7.34.2.7, 7.34.3.7, and 7.34.4.7 NMAC);
- Revisions of portions of the Medical Cannabis Advisory Board rule (7.34.2 NMAC), including modification of provisions concerning the number of Advisory Board members (in accordance with statute), removal of specialization requirements for members (in accordance with statute), and modification to the number of Advisory Board members required to achieve a quorum (in accordance with statute);
- Revisions to portions of the Registry Identification Card rule (7.34.3 NMAC), including but not limited to modifications to the lists of qualifying medical conditions, removal of the THC limit for cannabis-derived products (in accordance

with statute), removal of the replacement fee for registry identification cards (in accordance with statute), extension of the enrollment period from one year to three years (in accordance with statute), and removal of the prohibition of transfer of cannabis from a patient or primary caregiver to another patient or primary caregiver (in accordance with statute);

- Revisions to portions of the Licensing Requirements for Producers, Couriers, Manufacturers and Laboratories (7.34.4 NMAC), including but not limited to revision of the plant limit for licensed nonprofit producers, modification of the definition of “seedling” and inclusion of a provision to allow licensed nonprofit producers to possess unlimited numbers of seedlings (as that term is now defined), removal of the prohibition against volume discounts and promotional sales by LNPPs, removal of references to the previous THC limit for cannabis-derived products (in accordance with statute), modifications to LNPP licensing fees, inclusion of a provision recognizing the ability of either a qualified patient or primary caregiver to hold a personal production license (PPL) to grow cannabis for the qualified patient’s use, revisions concerning where a PPL holder may grow cannabis, revisions to identified bases for disciplinary actions against licensees, revisions to fines applicable to licensees for regulatory violations, and inclusion of an exemption from civil and criminal liability for public schools and school districts and their designated personnel to enable the administration of cannabis products to qualified students in public school settings in accordance with recent statutory changes.

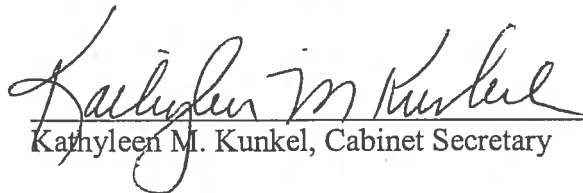
8. The Cabinet Secretary has reviewed the Report and Recommendation of the Hearing Officer and finds that the Hearing Officer has appropriately considered the proposed

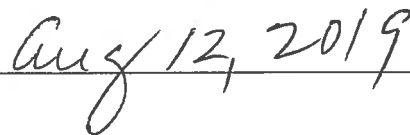
rule amendments and the substantive comments made through public comment, and the Secretary adopts the Hearing Officer's recommendations concerning the proposed rule amendments.

9. The Cabinet Secretary finds that the rule amendments are appropriate and consistent with authorizing laws, and the rule amendments are hereby adopted.

10. An emergency rule amendment to 7.34.4.8 NMAC was previously adopted by the Cabinet Secretary on March 1, 2019 and published in the NM Register, Vol. XXX, Issue 6, on March 26, 2019. By amending 7.34.4.8 NMAC within 180 days of the emergency rule amendment, in accordance with NMSA 1978, § 14-4-5, the Cabinet Secretary adopts a permanent rule that replaces the March 1, 2019 emergency rule amendment.

NEW MEXICO DEPARTMENT OF HEALTH


Kathyleen M. Kunkel, Cabinet Secretary


Date

2019 AUG 15 PM 4:30

This is an amendment to 7.34.4 NMAC, Sections 7, 8, 18, 19 and 23 through 25, effective 8/27/2019.

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 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, Subsection I of Section 26-2B-3 NMSA 1978 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 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. "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.

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

N. "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; [er]
- (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
- ~~(8)~~ (23) 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.

- O. "Department" means the department of health or its agent.
- P. "Facility" means any building, space, or grounds licensed for the production, possession, testing, manufacturing, or distribution of cannabis, concentrates, or cannabis-derived products.
- Q. "Intrastate" means existing or occurring within the state boundaries of New Mexico.
- R. "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.
- S. "License" means the document issued by the department granting the legal right to produce medical cannabis for a specified period of time.
- T. "Licensed producer" means a person or entity licensed to produce medical cannabis.
- U. "Licensure" means the process by which the department grants permission to an applicant to produce cannabis.
- V. "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.
- W. "Male plant" means a male cannabis plant.
- X. "Manufacture" means to make or otherwise produce cannabis-derived product or concentrate.
- 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.
- Z. "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.

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.

~~[FF.]~~ **GG.** “**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.

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

~~[HH.]~~ **II.** “**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.

~~[H.]~~ **JJ.** “**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.

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

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

~~[LL.]~~ **MM.** “**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.

~~[MM.]~~ **NN.** “**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.

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

~~[OO.]~~ **PP.** “**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.

~~[PP.]~~ **QQ.** “**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.

~~[QQ.]~~ **RR.** “**Qualified patient**” means a resident of New Mexico who has been diagnosed by a practitioner as having a debilitating medical condition and has received a registry identification card issued pursuant to the requirements of the act or department rules.

~~[RR.]~~ **SS.** “**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.

~~[SS.]~~ **TT.** “**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.

~~[TT.]~~ **UU.** “**Secretary**” means the secretary of the New Mexico department of health.

~~[UU.]~~ **VV.** “**Secure grounds**” means a facility that provides a safe environment to avoid loss or theft.

~~[VV.]~~ **WW.** “**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.

~~[WW.]~~ **XX.** “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.

~~[XX.]~~ **YY.** “Seedling” means a cannabis plant that has no flowers and that is less than 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.

~~[YY.]~~ **ZZ.** “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.

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

~~[AAA.]~~ **BBB.** “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.

~~[BBB.]~~ **DDD.** “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.

~~[CCC.]~~ **EEE.** “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.

~~[DDD.]~~ **FFF.** “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, 8/27/2019]

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 non-profit producer that operates a facility and, at any one time, is limited to a combined total of no greater than ~~[2,500 mature female plants, seedlings and mature male]~~ 1,750 cannabis 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 non-profit producer plant limit: The department may increase the cannabis plant limitation for a licensed non-profit producer in accordance with the following:

(1) Effective June 1, 2021, a non-profit producer may request an increase of up to 500 plants that exceeds the total plants allowed in Paragraph (2) of Subsection A of Section 7.34.4.8 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 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 department shall make a determination to approve or deny the non-profit producer's request to increase plant count based on the following factors:

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

(b) The non-profit 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 non-profit 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, a 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 Paragraph (2) of Subsection A of Section 7.34.4.8 NMAC, at any time. The 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 Paragraph (1) of Subsection B of Section 7.34.4.8 NMAC. The department shall only approve the request if the 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 non-profit producer shall provide objective data about the current supply in the medical cannabis market to demonstrate these factors. The department 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 subparagraph (2) of paragraph (A) above.

(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.

~~[B.]~~ C. Limitation on distribution: A non-profit 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.

~~[C.]~~ D. 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.

~~[D.]~~ E. 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.

[E.] F. 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.

[F.] G. 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.

[G.] H. 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.

[H.] I. 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.

~~[I.]~~ **J. 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.

~~[J.]~~ **K. 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.

~~[K.]~~ **L. 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, 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.

~~[L.]~~ **M. ~~[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 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.

~~[M.]~~ **N. 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.

~~[N.]~~ **O. 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.

[O.] P. 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.

[P.] Q. 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. 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.

[Q.] R. 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.

[R:] S. 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.

[S:] T. 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.

[T:] U. 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.

[U:] V. 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.

[V:] W. Fees applicable to applicants and licensees:

(1) **Non-profit producer application fee:** A 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 producer license fee:** A non-profit 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: ~~[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; 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.

~~[W-]~~ **X. 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, 8/27/2019]

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]~~.

C. No more than two personal production licenses may be issued for a given location, with proof that a second registered patient currently resides at the location. Multiple personal production licenses may not be issued for non-residential locations.

D. Qualified patients shall provide the following in order to be considered for a personal production license to produce medical cannabis:

(1) applicable non-refundable fee;

(2) a description of the single indoor or outdoor location that shall be used in the production of cannabis;

(3) if the location is on property that is not owned by the applicant: a written statement from the property owner or landlord that grants to the applicant permission to grow cannabis on the premises;

(4) a written plan that ensures that the cannabis production shall not be visible from the street or other public areas;

(5) a written acknowledgement that the applicant will ensure that all cannabis, cannabis-derived products and paraphernalia is accessible only by the applicant and their primary caregiver (if any), and kept secure and out of reach of children;

(6) a description of any device or series of devices that shall be used to provide security and proof of the secure grounds; and

(7) a written acknowledgement of the limitations of the right to use and possess cannabis for medical purposes in New Mexico.

[7.34.4.18 NMAC - Rp, 7.34.4.9 NMAC, 2/27/2015; A, 8/27/2019]

7.34.4.19 NON-PROFIT PRODUCER APPLICATION AND LICENSURE REQUIREMENTS: An applicant for initial or renewal non-profit producer licensure shall provide materials and information to the department, in accordance with the provisions of this section, in order to be considered for a license to produce

medical cannabis. A licensed non-profit producer shall also promptly submit revised versions of any such materials in the event that the materials or their content change.

A. Organizational information and materials: An applicant for non-profit producer licensure shall submit to the department:

- (1) proof that the private entity is a non-profit corporation in good standing with the NM secretary of state pursuant to Section 53-8-1 *et seq.*, NMSA 1978;
- (2) proof that the non-profit producer is in good standing with the New Mexico taxation and revenue department;
- (3) copies of the entity's articles of incorporation;
- (4) copies of the entity's by-laws;
- (5) verification that the board of directors of the non-profit includes, at a minimum, five voting members, including one medical provider limited to a physician (MD or OD), a registered nurse, nurse practitioner, licensed practical nurse, or physician assistant, and three patients currently qualified under department regulations and the Lynn and Erin Compassionate Use Act, Section 26-2B-1 *et seq.*, NMSA 1978;
- (6) a list of all persons or business entities having direct or indirect authority over the management or policies of the private entity;
- (7) a list of all persons or business entities having any ownership interest in any property utilized by the non-profit producer, whether direct or indirect, and whether the interest is in land, building(s), or other material, including owners of any business entity that owns all or part of land or building(s) utilized;
- (8) the identities and financial information, including information concerning loans and monetary investments, of all creditors currently holding a security interest in the non-profit producer or premises of the non-profit producer, if any; and
- (9) a business plan showing how the private entity intends to fund its operations and become a successful producer, including information concerning personnel, horticulture, technology, and funding sources.

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 [~~mature female plants, seedlings, and male~~] cannabis plants that the non-profit entity has been approved to produce as well as an inventory of usable cannabis that reflects current patient needs;
- (2) a production plan that includes the non-profit entity's plan for the growth, cultivation, and harvesting of medical cannabis;
- (3) a written set of distribution criteria for qualified patients or primary caregivers appropriate for cannabis services that describes the method by which and locations at which distribution will occur;
- (4) a complete written description of the means that the non-profit entity shall employ to safely dispense cannabis and cannabis-derived products to qualified patients and qualified patients' primary caregivers;
- (5) an attestation that qualified patients shall not be permitted to consume cannabis or cannabis-derived products on the entity's property;
- (6) an attestation that the entity will require the presentation of a department-issued identification card and a valid New Mexico photo identification card or a passport prior to selling or otherwise distributing cannabis or cannabis derived products to qualified patients and primary caregivers;
- (7) a description and sample of the packaging of the usable cannabis and cannabis-derived products that the non-profit producer shall utilize, including a label that satisfies the labeling requirements of this rule; and
- (8) a written quality assurance plan.

C. Facility information: An applicant for non-profit producer licensure shall submit to the department:

- (1) a description of the facilities and equipment that shall be used in the production and distribution of cannabis;
 - (2) proof that the facilities are not within 300 feet of any school, church, or daycare center;
- and
- (3) a description of the methods and device or series of devices that shall be used to provide security.

D. Educational methods and materials: An applicant for non-profit producer licensure shall submit to the department:

- (1) a description of the private entity's means for educating the qualified patient and the primary caregiver on the limitation of the right to possess and use cannabis;
- (2) a description of the means the private entity shall employ to make qualified patients or the primary caregiver aware of the quality of the product;
- (3) a description of ingestion options of usable cannabis provided by the private entity;
- (4) a description of inhalation techniques that shall be provided to qualified patients;
- (5) a description of potential side effects and how the private entity will educate qualified patients and the qualified patient's primary caregivers regarding potential side effects;
- (6) a description of the means the private entity shall employ to make qualified patients or the primary caregiver aware of how to report adverse events related to medical cannabis use; and
- (7) a description of the means the private entity shall employ to make qualified patients or the primary caregiver aware of how to report concerns regarding the private entity's products and services.

E. Sales record forms: A licensed non-profit producer that applies for renewal of licensure shall submit to the department a sample of the non-profit producer's sales record form(s), which shall identify (among other items) the name of the purchaser, the date of the sale, the quantity, and price of medical cannabis sold. A non-profit producer that applies for renewal of licensure shall additionally submit a profit and loss statement and balance sheet quarterly and as requested by the department.

F. Business licensure; TRD certificate: An applicant for non-profit producer licensure shall submit a current business license and tax and revenue registration certificate.

G. Policies and procedures: An applicant for non-profit producer licensure shall submit to the department copies of policies and procedures developed, implemented, and to be maintained on the premises of the private entity's facility. The applicant shall verify that the private entity will comply with the stated terms of the policies and procedures as written and submitted to the department.

H. Personnel records: An applicant for non-profit producer licensure shall submit to the department:

- (1) separate nationwide and statewide criminal history screening documentation, in accordance with the provisions of this rule;
- (2) samples of the personnel records to be retained by the private entity for each employee as required by this rule, including:
 - (a) a sample application for employment;
 - (b) state and federal employment documentation;
 - (c) a sample written job descriptions or employment contracts developed for all employee positions, to include duties, authority, responsibilities, qualifications, and supervision;
 - (d) payment or payroll records for all individuals associated with a non-profit producer renewal applicant's production and distribution facility, to include board members, persons having direct or indirect authority over management or policies, and employees submitted quarterly and as requested by the department.
- (3) an on-site training curriculum (unless the private entity intends to enter into contractual relationships with outside resources capable of meeting employee training needs) that addresses, at a minimum, the following topics:
 - (a) state and federal confidentiality laws, including the Health Insurance Portability and Accountability Act of 1996 (HIPAA);
 - (b) professional conduct and ethics;
 - (c) the Lynn and Erin Compassionate Use Act and department of health rules;
 - (d) informational developments in the field of medical use of cannabis; and
 - (e) employee safety and security training addressing, at a minimum, the proper use of the security measures and controls that have been adopted, and specific procedural instructions on how to respond to an emergency, including a robbery or violent accident.
- (4) proof of HIPAA certification for all individuals associated with the private entity, including all board members, persons having direct or indirect authority over management or policies, and employees.

I. Other materials: An applicant for non-profit producer licensure shall submit to the department:

- (1) a description of the department approved laboratory or laboratories that the non-profit entity will utilize for testing usable cannabis in accordance with this rule, and the type(s) of testing that the approved laboratory or laboratories will perform for the non-profit entity;

(2) the name of any courier that the non-profit entity intends to use for transport of usable cannabis to qualified patients and primary caregivers; and

(3) such other information as the private entity wishes to provide and such other information as the department may reasonably request.

J. Patient identification and sales records: A licensed non-profit producer shall retain clear, legible photocopies or electronic copies of current registry identification cards and current New Mexico photo identification cards of all qualified patients and primary caregivers served by the non-profit entity. A licensed non-profit producer shall also create and retain materials that document every instance in which usable cannabis was sold or otherwise distributed to another person or entity, including documentation of the recipient, type, quantity, and batch of the usable cannabis.

K. Material safety data sheets: A licensed non-profit producer shall maintain current material safety data sheets on-site for all chemicals used, including but not limited to cleaning compounds, sanitizing agents, and pesticides.

L. Local ordinance: A licensed non-profit producer shall comply with all applicable local ordinances, including but not limited to zoning, occupancy, licensing, and building codes.
[7.34.4.19 NMAC - Rp, 7.34.4.8 & 10 NMAC, 2/27/2015; A, 2/29/2016; A, 8/27/2019]

7.34.4.23 MONITORING AND CORRECTIVE ACTIONS:

A. Monitoring:

(1) The department or its designee may perform on-site assessments of a licensed producer or producer-applicant, an approved manufacturer or manufacturer-applicant, an approved laboratory or a laboratory-applicant, and an approved courier or courier-applicant, to determine compliance with these rules or submissions made pursuant to this rule. The department may enter the premises of a licensed producer, approved manufacturer, approved laboratory, or approved courier at any time to assess or monitor.

(2) 24 hours notice shall be provided to personal production license holders prior to an on-site assessment, except when the department has reasonable suspicion to believe that providing notice will result in the destruction of evidence, or that providing such notice will impede the department's ability to enforce these regulations.

(3) The department may review any and all records of a licensed non-profit producer, a qualified patient or primary caregiver, an approved manufacturer, approved laboratory, and approved courier, and may require and conduct interviews with such persons or entities and persons affiliated with such entities, for the purpose of determining compliance with department rules and applicable laws.

(4) All licensed producers, approved manufacturers, approved laboratories, and approved couriers shall provide the department or the department's designee immediate access to any material and information necessary for determining compliance with this rule.

(5) Failure by a licensed producer, approved manufacturer, approved laboratory, or approved courier to provide the department access to the premises or materials may result in disciplinary action(s), in accordance with this rule.

(6) Any failure to adhere to these rules that is documented by the department during monitoring may result in disciplinary action, in accordance with this rule.

(7) The department shall refer complaints alleging criminal activity that are made against a licensed producer, approved manufacturer, approved laboratory, or approved courier to appropriate New Mexico state or local law enforcement authorities.

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;
- (b) Total number of retail transactions;
- (c) Average amount (in units) purchased per retail transaction;
- (d) Number of units provided without charge;
- (e) Number of cannabis plants in production, including mature plants and seedlings;
- (f) Number of cannabis plants harvested;
- (g) Total yield of usable cannabis harvested from cannabis plants (in grams);
- (h) Average yield per plant (in grams);
- (i) Amount of cannabis (in grams) sold by wholesale;
- (j) Amount of cannabis (in grams) purchased by wholesale;
- (k) Number of live cannabis plants (including clones) and cannabis seeds sold;
- (l) Amount of dried cannabis leaves and flowers in stock;
- (m) Average price per gram of dried cannabis leaves and flowers;
- (n) Total amount of dried cannabis leaves and flowers sold (in units);
- (o) Total sales of dried cannabis leaves and flowers (in dollars and units);
- (p) Amount of cannabis derived products in stock (in units);
- (n) Total amount of cannabis derived products sold (in units);
- (o) Total sales of cannabis derived products (in dollars and units);
- (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.

C. Corrective action:

(1) If violations of requirements of this rule are cited as a result of monitoring or review of financial records, the licensed producer shall be provided with an official written report of the findings within seven business days following the monitoring visit or the review of financial records.

(2) Unless otherwise specified by the department, the licensed producer shall correct the violation within five calendar days of receipt of the official written report citing the violation(s).

(3) The violation shall not be deemed corrected until the department verifies in writing within seven calendar days of receiving notice of the corrective action that the corrective action is satisfactory.

(4) If the violation has not been corrected, the department may issue a notice of contemplated action to suspend, revoke, or take other disciplinary action against the producer's license, in accordance with the provisions of this rule.

D. Suspension of license without prior hearing: If immediate action is required to protect the health and safety of the general public, a qualified patient, or a primary caregiver, the program manager or designee may suspend the qualified patient, primary caregiver, or licensed producer's license without notice, and may immediately withdraw approval for a laboratory, manufacturer, or courier without notice.

(1) A licensee or approved entity whose license has been summarily suspended or whose approval has been withdrawn may request a record review in accordance with this part.

(2) The record review requested subsequent to a summary suspension shall be conducted by the administrative review committee.

(3) The administrative review committee shall conduct the record review on the summary suspension or withdrawal of approval by reviewing all documents submitted by both licensee and the department.

(4) The sole issue at a record review on a summary suspension or withdrawal of approval is whether the license shall remain suspended or whether the approval shall remain withdrawn pending a final adjudicatory hearing and subsequent ruling by the secretary.

(5) A licensee or approved entity given notice of summary suspension or summary withdrawal by the program may submit a written request for a record review. To be effective, the written request shall:

(a) be made within 30 calendar days, from the date of the notice issued by the department, as determined by the postmark;

(b) be properly addressed to the medical cannabis program;

(c) state the applicant's name, address, and telephone numbers;

(d) provide a brief narrative rebutting the circumstances of the suspension or withdrawal, and

(e) include attachments of any additional documentation that the individual or entity wishes to be considered in the record review.

[7.34.4.23 NMAC - Rp, 7.34.4.15 NMAC, 2/27/2015; A, 8/27/2019]

7.34.4.24 DISCIPLINARY ACTIONS AND APPEAL PROCESS:

A. **Grounds for disciplinary action:** 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, 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, 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 impede 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, 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.

B. Fines: Disciplinary actions against a licensed non-profit 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.

C. Persons and entities who may request a hearing: The following persons or entities may request a hearing to contest an action or proposed action of the department, in accordance with this rule:

- (1) a licensed producer whose license has been summarily suspended or who has received a notice of contemplated action to suspend, revoke, or take other disciplinary action;
- (2) a personal production licensure applicant whose application is denied for any reason other than failure to submit a completed application or failure to meet a submittal requirement of this rule;
- (3) an approved manufacturer whose approval status has been summarily suspended or who has received a notice of contemplated action to suspend, revoke, or take other disciplinary action;
- (4) a manufacturer-applicant whose application is denied for any reason other than failure to submit a completed application or failure to meet a submittal requirement of this rule;
- (5) an approved laboratory whose approval status has been summarily suspended or who has received a notice of contemplated action to suspend, revoke, or take other disciplinary action;
- (6) a laboratory-applicant whose application is denied for any reason other than failure to submit a completed application or failure to meet a submittal requirement of this rule;
- (7) an approved courier whose approval status has been summarily suspended or who has received a notice of contemplated action to suspend, revoke, or take other disciplinary action;
- (8) a courier-applicant whose application is denied for any reason other than failure to submit a completed application or failure to meet a submittal requirement of this rule; and
- (9) a person whose participation with a licensed producer or approved entity is prohibited based on a criminal background check.

D. Timing and content of request for hearing: The appellant shall file the request for hearing within 30 calendar days of the date the action is taken or the notice of contemplated action is received. The request shall:

- (1) be properly addressed to the medical cannabis program;
- (2) state the requestor's name, address, and telephone number(s); and
- (3) include a statement of the issue(s) that the appellant considers relevant to the review of the action.

E. Hearing process:

- (1) All hearings held pursuant to this section shall be conducted by a hearing officer appointed by the secretary.

(2) Hearings shall be conducted in Santa Fe, NM or, with the consent of the parties, in another location.

(3) Due to federal and state confidentiality laws, hearings held pursuant to this section that concern qualified patients, patient-applicants, licensed producers or producer-applicants, shall be closed to the public. Portions of hearings may further be closed to prevent the disclosure of confidential information.

(4) The hearing shall be recorded on audiotape or other means of sound reproduction.

(5) Any hearing provided for in this rule may be held telephonically, with the consent of the parties.

F. Scheduling: The department shall schedule and hold the hearing as soon as practicable, however; in any event no later than 60 calendar days from the date the department receives the appellant's request for hearing. The hearing examiner shall extend the 60 day time period upon motion for good cause shown or the parties may extend the 60 day time period by mutual agreement. The department shall issue notice of hearing, which shall include:

(1) a statement of the location, date, and time of the hearing;

(2) a short and plain statement of the legal authority under which the hearing is to be held;

(3) a short and plain statement of the subject of the hearing.

G. Presentation of evidence: All parties shall be given the opportunity to respond and present evidence and argument on all relevant issues.

H. Record of proceeding: The record of the proceeding shall include the following:

(1) all pleadings, motions, and intermediate rulings;

(2) evidence and briefs received or considered;

(3) a statement of matters officially noticed;

(4) offers of proof, objections, and rulings thereon;

(5) proposed findings and conclusions; and

(6) any action recommended by the hearing examiner.

I. Audio recording: A party may request a copy of the audio recording of the proceedings.

J. Procedures and evidence:

(1) A party may be represented by a person licensed to practice law in New Mexico or a non-lawyer representative, or may represent himself or herself.

(2) The rules of evidence as applied in the courts do not apply in these proceedings. Any relevant evidence shall be admitted. Irrelevant, immaterial, or unduly repetitious evidence may be excluded.

(3) The experience, technical competence, and specialized knowledge of the hearing examiner, the department or the department's staff may be used in the evaluation of evidence.

(4) An appellant's failure to appear at the hearing at the date and time noticed for the hearing shall constitute a default.

K. Conduct of proceeding: Unless the hearing examiner determines that a different procedure is appropriate, the hearing shall be conducted in accordance with the procedures set forth in this rule. The following procedures shall apply:

(1) the appellant shall present an opening statement and the department may present an opening statement or reserve the statement until presentation of the department's case;

(2) after the opening statements, if made, the appellant shall present its case;

(3) upon the conclusion of the appellant's case, the department shall present its case;

(4) upon conclusion of the appellee's case, the appellant may present rebuttal evidence; and

(5) after presentation of the evidence by the parties, the parties may present closing argument.

L. Burden of proof: The appellant shall bear the burden of establishing by a preponderance of the evidence that the decision made or proposed by the department should be reversed or modified.

M. Continuances: The hearing examiner may grant a continuance for good cause shown. A motion to continue a hearing shall be made at least 10 calendar days before the hearing date.

N. Telephonic hearings:

(1) Any party requesting a telephonic hearing shall do so no less than 10 business days prior to the date of the hearing. Notice of the telephonic hearing shall be given to all parties and shall include all necessary telephone numbers.

(2) The appellant is responsible for ensuring the telephone number to the appellant's location for the telephonic hearing is accurate and the appellant is available at said telephone number at the time the hearing

is to commence. Failure to provide the correct telephone number or failure to be available at the commencement of the hearing shall be treated as a failure to appear and shall subject the appellant to a default judgment.

(3) The in-person presence of some parties or witnesses at the hearing shall not prevent the participation of other parties or witnesses by telephone with prior approval of the hearing examiner.

O. Recommended action and final decision:

(1) The parties may submit briefs including findings of fact and conclusions of law for consideration by the hearing examiner.

(2) No later than 30 calendar days after the last submission by a party, the hearing examiner shall prepare and submit to the secretary a written recommendation of action to be taken by the secretary. The recommendation shall propose sustaining, modifying, or reversing the action or proposed action of the department.

(3) The secretary shall issue a final written decision accepting or rejecting the hearing examiner's recommendation in whole or in part no later than 30 calendar days after receipt of the hearing examiner's recommendation. The final decision shall identify the final action taken. Service of the secretary's final decision shall be made upon the appellant by registered or certified mail.

(4) The final decision or order shall be included in a producer's file with the medical cannabis program.

[7.34.4.24 NMAC - Rp, 7.34.4.16 NMAC, 2/27/2015; A, 8/27/2019]

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

A. No officer, employee, or approved contractor of a licensed producer, approved manufacturer, approved courier, or approved laboratory, nor any qualified patient licensed as a producer or enrolled primary caregiver, shall be subject to arrest, prosecution, or penalty in any manner for the production, possession, distribution, or dispensation of cannabis in accordance with this rule and the act. For the purpose of this section, the department deems approved manufacturers, approved couriers, and approved laboratories to be ancillaries of licensed non-profit producers, entitled to the protections from criminal liability identified for licensed producers in the Lynn and Erin Compassionate Use Act, Section 26-2B-4 NMSA 1978.

B. Any property interest that is possessed, owned, or used in connection with the production of cannabis or acts incidental to such production shall not be harmed, neglected, injured, or destroyed while in the possession of state or local law enforcement officials. Any such property interest shall not be forfeited under any state or local law providing for the forfeiture of property except as provided in the Forfeiture Act. Cannabis, paraphernalia or other property seized from a qualified patient or primary caregiver in connection with the claimed medical use of cannabis shall be returned immediately upon the determination by a court or prosecutor that the qualified patient or primary caregiver is entitled to the protections of the provisions of this rule and act as shall be evidenced by a failure to actively investigate the case, a decision not to prosecute, the dismissal of charges, or acquittal.

C. In accordance with the Public School Code, Chapter 22 NMSA 1978, and the Lynn and Erin Compassionate Use Act at Subsection G of Section 26-2B-4 NMSA 1978, 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, 8/27/2019]