TITLE 7 HEALTH
CHAPTER 34 MEDICAL USE OF CANNABIS
PART 4 LICENSING REQUIREMENTS FOR PRODUCERS, COURIERS, MANUFACTURERS AND LABORATORIES

7.34.4.1 ISSUING AGENCY: New Mexico Department of Health, Medical Cannabis Program.
[7.34.4.1 NMAC - Rp, 7.34.4.1 NMAC, 2/27/2015]

7.34.4.2 SCOPE: This rule applies to all licensed producers of medical use cannabis, defined in Section 26-2B-3 (D) NMSA 1978 as "any person or association of persons within New Mexico that the department determines to be qualified to produce, possess, distribute, and dispense cannabis pursuant to the Lynn and Erin Compassionate Use Act and that is licensed by the department."
[7.34.4.2 NMAC - Rp, 7.34.4.2 NMAC, 2/27/2015]

7.34.4.3 STATUTORY AUTHORITY: The requirements set forth herein are promulgated by the secretary of the department of health (DOH) pursuant to the authority granted under Section 9-7-6 (E) NMSA 1978, and the Lynn and Erin Compassionate Use Act, 26-2B-1 *et seq*., NMSA 1978. Although federal law currently prohibits any use of cannabis, the laws of several states permit the medical use and cultivation of cannabis. New Mexico joins this effort to provide for the health and welfare of its citizens. New Mexico adopts these regulations to accomplish the purpose of the Lynn and Erin Compassionate Use Act as stated in Section 26-2B-2 NMSA 1978, "to allow for the beneficial use of medical cannabis in a regulated system for alleviating symptoms caused by debilitating medical conditions and their medical treatments," while at the same time ensuring proper enforcement of any criminal laws for behavior that has been deemed illicit by the state.
[7.34.4.3 NMAC - Rp, 7.34.4.3 NMAC, 2/27/2015]

7.34.4.4 DURATION: Permanent.
[7.34.4.4 NMAC - Rp, 7.34.4.4 NMAC, 2/27/2015]

7.34.4.5 EFFECTIVE DATE: February 27, 2015, unless a later date is cited at the end of a section.
[7.34.4.5 NMAC - Rp, 7.34.4.5 NMAC, 2/27/2015]

7.34.4.6 OBJECTIVE: Ensuring the safe production, distribution, and dispensation of cannabis for the sole purpose of medical use for alleviating symptoms caused by debilitating medical conditions in a regulated system.
[7.34.4.6 NMAC - Rp, 7.34.4.6 NMAC, 2/27/2015]

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 imposition of a summary suspension, in accordance with department rules. The administrative review committee shall consist of the chief medical officer of the department (or that's person's designee); a deputy secretary of the department (or that person's designee), and the chief nursing officer of the department (or that person's designee).

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

E. "Advisory board" means the medical cannabis advisory board consisting of eight practitioners representing the fields of neurology, pain management, medical oncology, psychiatry, infectious disease, family medicine, and gynecology.

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 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 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.

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.

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; or

(8) any other medical condition, medical treatment, or disease as approved by the department which results in pain, suffering, or debility for which there is credible evidence that medical use cannabis could be of benefit.

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.

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. "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. "Patient enrollment/re-enrollment form" means the registry identification card application form for patient applicants provided by the medical cannabis program.

HH. "Personal production license" means a license issued to a qualified patient participating in the medical cannabis program, to permit the qualified patient to produce medical cannabis for the qualified patient's personal use, consistent with the requirements of department rule.

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

JJ. "Plant" means any cannabis plant, cutting, or clone that has roots or that is cultivated with the intention of growing roots.

KK. "Policy" means a written statement of principles that guides and determines present and future decisions and actions of the licensed producer.

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

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

NN. "Primary caregiver application form" means the registry identification card application form provided by the medical cannabis program.

OO. "Private entity" means a private, non-profit organization that applies to become or is licensed as a producer and distributor of cannabis, concentrates, or cannabis-derived products.

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

QQ. "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. "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. "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. "Secretary" means the secretary of the New Mexico department of health.

UU. "Secure grounds" means a facility that provides a safe environment to avoid loss or theft.

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

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

XX. "Seedling" means a cannabis plant that has no flowers.

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

ZZ. "THC" means tetrahydrocannabinol, a cannabinoid that is the primary psychoactive ingredient in cannabis.

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

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

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

DDD. "Usable cannabis" means the dried leaves and flowers of the female cannabis plant and cannabis-derived products, including concentrates, but does not include the seeds, stalks, or roots of the plant.

[7.34.4.7 NMAC - Rp, 7.34.4.7 NMAC, 2/27/2015]

7.34.4.8 PRODUCER LICENSING; GENERAL PROVISIONS:

A. The department may license two classes of producers:

(1) A qualified patient who holds a valid personal production license. A qualified patient who holds a valid personal production license is authorized to possess no more than four mature female plants and a combined total of 12 seedlings and male plants, and may possess no more than an adequate supply of usable cannabis, as specified in department rule. A personal production license holder may additionally obtain usable cannabis, seeds, or plants from licensed non-profit producers. The primary caregiver of a qualified patient who holds a personal production license may assist the qualified patient to produce medical cannabis at the designated licensed location that is identified on the personal production license; the primary caregiver may not independently produce medical cannabis.

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

B. 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. 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. 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. 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 rule, 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 shall not identify any person as an intended recipient of usable cannabis who is not either a qualified patient or primary caregiver.

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

(1) contacting the applicant by telephone, mail, or electronic mail;

(2) conducting an on-site visit;

(3) requiring a face-to-face meeting and the production of additional identification materials if proof of identity is uncertain; and

(4) requiring additional relevant information as the department deems necessary.

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

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

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

(2) Disqualifying convictions: Individuals convicted of a felony violation of Section 30-31-20 (trafficking of a controlled substance); 30-31-21 (distributing a controlled substance to a minor); 30-31-22 NMSA 1978 (distributing a controlled substance); or a violation of any equivalent federal statute or equivalent statute from any other jurisdiction, shall be prohibited from participating or being associated with either a non-profit producer licensed under this rule, an approved laboratory, an approved manufacturer, or an approved courier. If an individual has been convicted of a felony violation of the NM Controlled Substances Act other than Sections 30-31-20 through 30-31-22 NMSA 1978, or has been convicted of any equivalent federal statute or equivalent statute from any other jurisdiction, and the final completion of the entirety of the associated sentence of such conviction has been less than five years from the date of the individual's anticipated association with the production facility, then the individual shall be prohibited from serving on the board of a licensed non-profit producer, or working for the licensed producer, or approved entity. An individual who is disqualified shall be notified of his or her disqualification. If an individual has been convicted of more than one felony violation of the above-cited sections of the NM Controlled Substances Act or an equivalent federal statute or equivalent statute from any other jurisdiction, the individual shall be notified that he or she is permanently prohibited from participating or being associated with a licensed non-profit producer, approved manufacturer, approved laboratory, or approved courier. Any violation of this subsection shall result in the immediate revocation of any privilege granted under this rule and the act.

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

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

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

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

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

K. Limitation on sales within 90 consecutive calendar days: A licensed non-profit producer shall not sell or distribute usable cannabis to a qualified patient or primary caregiver in a total quantity that exceeds 230 units, 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. 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.

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

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

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

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

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

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

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

(a) job descriptions or employment contracts developed for every employee that identify duties, authority, responsibilities, qualifications, and supervision; and

(b) training materials concerning adherence to state and federal confidentiality laws.

(6) personnel records for each employee that include an application for employment and a record of any disciplinary action taken;

(7) on-site training curricula, or contracts with outside resources capable of meeting employee training needs, to include, at a minimum, the following topics:

(a) professional conduct, ethics, and patient confidentiality; and

(b) informational developments in the field of medical use of cannabis.

(8) employee safety and security training materials provided to each employee at the time of his or her initial appointment, to include:

(a) training in the proper use of security measures and controls that have been adopted; and

(b) specific procedural instructions regarding how to respond to an emergency, including robbery or a violent accident.

(9) a general written security policy, to address at a minimum:

(a) safety and security procedures;

(b) personal safety; and

(c) crime prevention techniques.

(10) training documentation prepared for each employee and statements signed by employees indicating the topics discussed (to include names and titles of presenters) and the date, time, and place the employee received said training;

(11) a written policy regarding the right of the private entity to refuse service;

(12) a confidentiality policy to ensure that identifying information of qualified patients is not disclosed or disseminated without authorization from the patient, except as otherwise required by the department; and

(13) such other policies or procedures as the department may require.

O. 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. 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.

(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. 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. 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. 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. 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. 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. 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) for the first 150 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.

(3) 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.

(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.

(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. 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]

7.34.4.9 NON-PROFIT PRODUCER TESTING OF USABLE CANNABIS: All dried usable cannabis and all concentrated cannabis derived products produced, sold, or distributed by a non-profit producer shall be sampled for testing purposes by the licensed non-profit producer, and those samples shall be tested by an approved laboratory, consistent with the requirements of this rule, prior to the sale or distribution of the dried usable cannabis or concentrated cannabis derived product. Each batch of dried usable cannabis or cannabis concentrate shall be segregated and sampled, and each sample shall be tested by an approved laboratory in accordance with the testing requirements of this rule, and determined by the licensed non-profit producer to have passed the following individual testing requirements, before dried usable cannabis or cannabis concentrate from that batch is made available for sale or distribution.

A. Exception; staggered implementation: The department may waive testing requirement(s) of this section, in whole or in part, if the department determines that the number of laboratories approved to conduct a given test is insufficient for all testing samples to be appropriately processed. The department may also adopt and enforce a staggered, random testing schedule for the sampling and testing of dried, usable cannabis and concentrated cannabis derived products by licensed non-profit producers.

B. Exception for previously tested cannabis: A non-profit producer shall not be required to sample and test cannabis or a concentrated cannabis-derived product if the batch was previously sampled, and the sample was tested by another non-profit producer and determined to have passed the testing requirements of this rule.

C. Individual testing requirements:

(1) Microbiological test: A non-profit producer shall sample and test dried, usable cannabis and concentrated cannabis derived products for microbiological contaminants, using an approved laboratory. A dried cannabis sample may be deemed to have passed the microbiological test if it satisfies the standards set forth in Section 2023 of the United States Pharmacopeia ("microbiological attributes of non-sterile nutritional and dietary supplements"), which can be obtained at http://www.usp.org.

(2) Mycotoxin test: A non-profit producer shall sample and test dried, usable cannabis and concentrated cannabis derived products for mycotoxins, using an approved laboratory. A sample may be deemed to have passed the mycotoxin test if the total quantity of aflatoxin B1, B2, G1, and G2 and ochratoxin A is collectively less than 20 µg/kg (parts per billion) of the sample.

(3) Solvent residue test: A non-profit producer shall sample and test all concentrated cannabis derived products that are manufactured using solvent extraction methods for the presence of solvent residue, using an approved laboratory. A non-profit producer shall determine on the basis of the solvent residue test results whether the quantity of solvent residue contained within a concentrated cannabis derived product poses a health risk to consumers. A non-profit producer shall not sell or distribute a concentrated cannabis derived product from a batch that is found to contain a quantity of solvent residue that is likely to be harmful to human health.

(4) Heavy metals test: A non-profit producer shall sample and test dried, usable cannabis and concentrated cannabis derived products for heavy metals. A sample may be deemed to have passed the heavy metals test if the total quantity of arsenic is less than 0.14 µg/kg (parts per billion); if the total quantity of cadmium is less than 0.09 µg/kg; if the total quantity of lead is less than 0.29 µg/kg; and if the total quantity of mercury is less than 0.29 µg/kg. Exception: a non-profit producer that grows cannabis in a hydroponic system utilizing either a municipal water supply or a water filtering system sufficient to filter the contaminants identified above shall not be subject to heavy metals test requirements.

(5) Quantity of THC and CBD: A non-profit producer shall sample and test all dried usable cannabis and concentrated cannabis derived products for quantity of THC and CBD, using an approved laboratory, prior to sale, distribution, or other use.

(6) Additional testing: The department may require additional testing of cannabis and cannabis derived products by non-profit producers, as it deems appropriate.

D. Release of batch after testing: A licensed non-profit producer may release an entire batch of dried cannabis or concentrated cannabis derived product for immediate manufacture, sale, or other use, provided that the sample taken from the batch passes the tests required in this section.

E. Procedures for testing: A licensed non-profit producer shall ensure that the following testing procedures are followed:

(1) sampling and segregation: a licensed non-profit producer shall remove a sample of no less than three grams from every batch of harvested, dried, usable cannabis, and no less than one gram from every batch of concentrated cannabis-derived product, and transfer the sample to an approved laboratory for testing; the remainder of the batch of dried, usable cannabis or concentrated cannabis-derived product shall be segregated until the licensed non-profit producer receives the results of laboratory testing report and determines whether the batch meets the testing requirements of this rule;

(2) documentation: a licensed non-profit producer shall appropriately document the sampling and testing of all dried cannabis and concentrated cannabis-derived product, and shall utilize a department approved laboratory for the purpose of testing usable cannabis;

(3) remediation: if a sample does not pass testing, the producer shall determine whether remediation is appropriate and test another sample from the batch at issue, or identify processes that will render the dried cannabis or cannabis-derived product safe and retest in accordance with the requirements of this section;

(4) notice and destruction: if the batch cannot be remediated to where it meets the testing requirements of this rule, the non-profit producer shall notify the medical cannabis program within 24 hours, and confirm the destruction and disposal of the dried cannabis or concentrated cannabis-derived product;

(5) testing and remediation protocols: a licensed non-profit producer shall adopt and maintain on the premises protocols regarding sampling, sample testing, remediation, and retesting, consistent with this rule;

(6) preservation and inspection of testing records: a licensed non-profit producer shall maintain all results of laboratory tests conducted on cannabis or cannabis derived products produced by the licensed non-profit producer or its contractor for a period of at least two years, and shall make those results available to qualified patients and primary caregivers enrolled in the medical cannabis program upon request; and

(7) disciplinary action: repeated failure to pass testing may result in the imposition of disciplinary action(s) by the department, consistent with this rule.

[7.34.4.9 NMAC - Rp, 7.34.4.8 NMAC, 2/27/2015]

7.34.4.10 COMPLAINT PROCEDURE; DEPARTMENT TESTING: If the department or its designee receives a complaint regarding the presence of mold, bacteria, or another contaminant in cannabis produced by a licensed non-profit or patient who holds a personal production license, or if the department or its designee has reason to believe that the presence of mold, bacteria, or another contaminant may jeopardize the health of a patient, the department or its designee may conduct an unannounced visit to the producer and may require the producer to provide samples of medical cannabis for testing by the department. Producers shall bear the cost of any testing required by the department. Medical cannabis program employees or their designees may possess those medical cannabis samples for the sole purposes of testing or transport to a testing facility. The department or its designee shall comply with the following testing requirements:

A. the department or its designee shall maintain chain of custody documentation for any medical cannabis samples taken;

B. a written receipt shall be given to the producer for all testing samples;

C. all testing samples shall be placed into a sealed container and clearly labeled;

D. all testing samples shall be tested by the department or a designated testing facility;

E. no more than eight grams of medical cannabis shall be gathered for testing purposes from a non-profit medical cannabis producer on any single occasion; and

F. no more than one gram of medical cannabis shall be gathered for testing purposes from a patient who holds a personal production license on any single occasion.

[7.34.4.10 NMAC - Rp, 7.34.4.8 NMAC, 2/27/2015]

7.34.4.11 USE OF PESTICIDES BY LICENSED PRODUCERS: The use of any pesticide by a licensed producer in the growth or manufacture of cannabis shall be in accordance with the New Mexico Pesticide Control Act, Section 76-4-1 *et seq.*, NMSA 1978, and associated regulations.

[7.34.4.11 NMAC - N, 2/27/2015]

7.34.4.12 DEPARTMENT APPROVAL OF MANUFACTURERS OF CANNABIS DERIVED PRODUCTS; GENERAL PROVISIONS:

A. Submittal of applications: A manufacturer applicant shall submit an authorized application form to the program with each initial application and renewal application, together with a fee of one thousand dollars ($1,000) issued to the medical cannabis program. A manufacturer applicant shall comply with the application requirements of this rule, and shall submit such other information as the manufacturer applicant wishes to provide or such information as the department may request for initial approval or periodic evaluation(s) during the approval period.

B. Application requirements: A manufacturer applicant shall submit to the department:

(1) proof that the manufacturer applicant is in good standing with the New Mexico taxation and revenue department;

(2) copies of the manufacturer applicant's articles of incorporation and by-laws, as applicable;

(3) a complete written description of the means that the manufacturer applicant shall employ to safely manufacture cannabis-derived products, including but not limited to hygiene standards consistent with the requirements of this rule;

(4) a list of all persons or business entities having direct or indirect authority over the management or policies of the manufacturer applicant;

(5) a list of all persons or business entities having any ownership interest in any property utilized by the manufacturer applicant, 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;

(6) a description of the facilities that shall be used in the manufacture of cannabis derived products;

(7) a description of how the manufacturer applicant will obtain cannabis or cannabis concentrates from a licensed non-profit producer, and how the manufacturer applicant will transport cannabis derived products to a licensed non-profit producer, including but not limited to chain of custody documentation;

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

(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) an attestation that no firearms will be permitted on any premises used for manufacture of cannabis derived products by the manufacturer applicant;

(11) a description of the methods and device or series of devices that shall be used to provide security;

(12) training documentation prepared for each employee of the manufacturer applicant, 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;

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

(a) job descriptions or employment contracts developed for every employee of the manufacturer applicant that identify duties, authority, responsibilities, qualifications, and supervision; and

(b) training materials concerning adherence to state and federal confidentiality laws.

(14) personnel records for each employee of the manufacturer applicant that include an application for employment and a record of any disciplinary action taken;

(15) employee safety and security training materials provided to each employee of the manufacturer applicant 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.

(16) such other materials as the department may require.

C. Packaging and labeling: a manufacturer applicant shall submit a description and sample of the opaque, child resistant packaging of the concentrate or cannabis-derived product that the manufacturer shall utilize, including a label that shall contain:

(1) the name of the entity that produced the cannabis and the name of the manufacturer;

(2) a batch number or code;

(3) a production date or expiration date, including a "use by" or "freeze by" date for products capable of supporting the growth of infectious, toxigenic, or spoilage microorganisms;

(4) a description of the number of units of usable cannabis contained within the product;

(5) instructions for use;

(6) warnings for use;

(7) instructions for appropriate storage;

(8) approved laboratory analysis, including the results of strength and composition within ten percent (10%) of numbers shown on the package;

(9) the name of the strain, product facts, or a nutrition fact panel, and a statement that the product is for medical use by qualified patients, to be kept away from children, and not for resale; and

(10) the name of the department approved testing facility or facilities used for ingredient testing, and the type(s) of testing conducted.

D. Term of approval: Department approval of a manufacturer shall be for a term of one year, and shall expire after that year, or upon closure of the manufacturer. An approved manufacturer shall apply for renewal of approval annually no later than 30 days prior to expiration.

E. Identification cards: Identification cards issued by the department are the property of the department and shall be returned to the department upon termination of the holder's employment with the approved laboratory, suspension, or revocation of approval by the department, or upon demand of the department.

[7.34.4.12 NMAC - N, 2/27/2015]

7.34.4.13 STANDARDS FOR MANUFACTURE OF CANNABIS-DERIVED PRODUCTS: The following are minimum requirements for the manufacture of cannabis-derived products which shall apply to all manufacturers:

A. General requirements: A licensed non-profit producer and a manufacturer shall take reasonable measures and precautions to ensure the following:

(1) that all manufacturing shall be done in premises that are in compliance with local ordinances, including but not limited to zoning, occupancy, licensing, and building codes;

(2) that the manufacturing operation and all equipment, implements, and fixtures shall be used exclusively for the production of cannabis derived products and that food processing for personal, staff, or the general public shall be prohibited;

(3) that all non-profit producer and manufacturer staff involved in the handling, transportation, manufacture, testing, or packaging of cannabis derived products must complete general food handler safety training, such as is commonly available online for a nominal fee;

(4) that any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including a boil, sore, or infected wound, or any other abnormal source of microbial contamination for whom there is a reasonable possibility of contact with preparation surfaces for medical cannabis or cannabis derived products, shall be excluded from any operations which may be anticipated to result in such contamination until the condition is corrected;

(5) that hand-washing facilities are adequate and convenient, and that they are furnished with running water at a suitable temperature; hand-washing facilities shall be located in the facility in medical cannabis derived product preparation areas and where good sanitary practices require employees to wash or sanitize their hands, and provide effective hand-cleaning and sanitizing preparations, and sanitary towel service or suitable drying devices;

(6) that all persons involved in preparing or handling medical cannabis or cannabis derived products at the manufacturing operation conform to hygienic practices while on duty, including:

(a) maintaining adequate personal cleanliness;

(b) washing hands thoroughly in an adequate hand-washing area before starting work, and at any other time when the hands may have become soiled or contaminated;

(c) refraining from preparing or handling medical cannabis or cannabis derived products if the handler has or may have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, until such condition is corrected;

(d) complying with the other requirements of this section.

(7) that there is sufficient space for placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations for production of medical cannabis derived products;

(8) that litter and waste are properly removed, and the operating systems for waste disposal are maintained in an adequate manner so that they do not constitute a source of contamination in areas where medical cannabis or cannabis derived products are exposed;

(9) that floors, walls, and ceilings are constructed in such a manner that they may be adequately cleaned, kept clean, and kept in good repair;

(10) that there is adequate safety-type lighting in all areas where medical cannabis or cannabis derived products are processed or stored, and where equipment or utensils are cleaned;

(11) that the manufacturer provides adequate screening or other protection against the entry of pests; rubbish shall be disposed of so as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage, or breeding place for pests;

(12) that building, fixtures, and other physical facilities where cannabis derived products are manufactured are maintained in a sanitary condition;

(13) that all contact surfaces, including utensils and equipment used for preparation of cannabis derived products are cleaned and sanitized as frequently as necessary to protect against contamination;

(14) that all equipment and utensils used for preparation of cannabis derived products are designed and of such material and workmanship as to be adequately cleanable, and are properly maintained;

(15) that only environmental protection agency (EPA) registered sanitizing agents are used in manufacturing operations and that they are used in accordance with labeled instructions;

(16) that toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of medical cannabis or cannabis derived products;

(17) that the water supply is sufficient for the operations intended and is derived from a source that is a regulated water system; private water supplies shall be from a water source that is capable of providing a safe, potable, and adequate supply of water to meet the manufacturing facility's needs;

(18) that plumbing shall be of adequate size and design, adequately installed, and maintained to carry sufficient quantities of water to required locations throughout the facility; and properly convey sewage and liquid disposable waste from the facility;

(19) that there are no cross-connections between the potable and waste water lines;

(20) that the manufacturer provide its employees with adequate, readily accessible toilet facilities that are maintained in a sanitary condition and good repair;

(21) that all operations in the receipt, inspection, transport, segregation, preparation, manufacture, packaging, and storage of medical cannabis or cannabis derived products are conducted in accordance with adequate security and sanitation principles;

(22) that medical cannabis or cannabis derived products that can support the rapid growth of undesirable microorganisms are stored and transported in a manner that prevents the growth of these microorganisms;

(23) that storage and transportation of medical marijuana or cannabis derived products are under conditions that will maintain security and protect medical cannabis or cannabis derived products against physical, chemical, and microbial contamination as well as against deterioration of the medical cannabis or cannabis derived product and the container;

(24) that current material safety data sheets are kept on the premises for all chemicals used, including but not limited to cleaning compounds, sanitizing agents, and pesticides; and

(25) that extraction for the purpose of manufacturing concentrates is conducted in a closed system utilizing an oil extractor solvent such as N-butane or carbon dioxide or utilizing ethyl alcohol.

B. Prohibited products: The use of dimethylsulfoxide (DMSO) in the production of cannabis derived products, and the possession of DMSO upon the premises of a manufacturer, is prohibited.

[7.34.4.13 NMAC - N, 2/27/2015]

7.34.4.14 LABELING OF USABLE CANNABIS: A non-profit producer shall not sell or otherwise distribute a usable cannabis product that has not been packaged and labeled in accordance with this rule. The label shall identify:

A. the name of the entity that produced the cannabis, and the name of the manufacturer of the cannabis-derived product (as applicable);

B. a batch number or code;

C. a production date or expiration date, including a "use by" or "freeze by" date for products capable of supporting the growth of infectious, toxigenic, or spoilage microorganisms;

D. the number of units of usable cannabis or concentrated cannabis-derived product contained within the product, as identified in department rules for the enrollment of qualified patients;

E. for dried, usable cannabis: the quantity of THC and CBD, which shall be expressed by weight;

F. for concentrated cannabis derived product: the quantity of THC and CBD, which shall be expressed by weight and by percentage of total weight;

G. instructions for use;

H. warnings for use;

I. instructions for appropriate storage;

J. approved laboratory analysis, including the results of strength and composition within ten percent (10%) of numbers shown on the package;

K. the name of the strain, product facts, or a nutrition fact panel, and a statement that the product is for medical use by qualified patients, to be kept away from children, and not for resale;

L. whether the batch from which the product was derived was sampled and tested by an approved laboratory; and

M. the name of the department approved testing facility used for active ingredient analysis, and quantity of THC and CBD (as applicable).

[7.34.4.14 NMAC - N, 2/27/2015]

7.34.4.15 DEPARTMENT-APPROVED TESTING LABORATORIES; GENERAL PROVISIONS: A laboratory applicant shall comply with the application requirements of this rule, and shall submit such other information as the laboratory applicant wishes to provide or such information as the department may request for initial approval and periodic evaluations during the approval period.

A. Testing categories: A laboratory may apply to become approved by the department as an approved laboratory for the testing of cannabis and cannabis derived products in all or any one of the following categories:

(1) mycotoxin analysis;

(2) microbiological contaminant analysis;

(3) solvent residue analysis;

(4) heavy metals analysis;

(5) quantity of THC and CBD; and

(6) such other testing categories as the department may identify.

B. Fee: A laboratory applicant shall submit to the program with each initial application and renewal application for continued approval a non-refundable application fee of two-thousand-two-hundred dollars ($2,200), payable to the medical cannabis program.

C. Application materials: A laboratory applicant shall submit to the program with each initial application and renewal application for continued approval the following:

(1) standard operating procedures to be followed by the laboratory, including but not limited to policies and procedures to be used in performing analysis of samples;

(2) a description of the type of tests to be conducted by the laboratory applicant, which may include, but are not limited to, testing for microbiological contaminants, mycotoxins, solvent residue, heavy metals, THC content, CBD content, identity, purity, strength, composition, or nutritional content, and other quality factors;

(3) quality control criteria for the test(s) that the applicant intends to conduct;

(4) evidence that validates the accuracy of the test(s) to be conducted by the laboratory applicant as performed in the applicant's laboratory;

(5) proof that the laboratory applicant is in good standing with the New Mexico taxation and revenue department;

(6) copies of the laboratory applicant articles of incorporation and by-laws, as applicable;

(7) a list of all persons or business entities having direct or indirect authority over the management or policies of the laboratory applicant;

(8) a list of all persons or business entities having any ownership interest in any property utilized by the laboratory applicant, 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;

(9) a description of the facilities and equipment that shall be used in the operation of the laboratory applicant;

(10) a description of how the laboratory applicant will ensure and document chain of custody of any samples held or tested by the laboratory;

(11) a general written security policy, to address at a minimum safety and security procedures;

(12) an attestation that no firearms will be permitted on any premises used by the laboratory applicant;

(13) a description of the methods and device or series of devices that shall be used to provide security;

(14) training documentation prepared for each employee of the laboratory applicant, 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;

(15) personnel records for each employee of the manufacturer applicant that include an application for employment and a record of any disciplinary action taken;

(16) employee safety and security training materials provided to each employee of the manufacturer applicant at the time of his or her initial appointment, to include training in the proper use of security measures and controls that have been adopted, and specific procedural instructions regarding how to respond to an emergency, including robbery or a violent accident; and

(17) such other materials as the department may require.

D. Materials to be maintained on premises: An approved laboratory shall maintain on its premises, and shall promptly present to the department upon request:

(1) personnel documentation including, but not limited to employment records, job descriptions, education, and training requirements of the laboratory, and documentation of education and training provided to staff for the purpose of performance of assigned functions;

(2) requirements concerning laboratory operations, business licensing, and security procedures;

(3) standards for receipt, handling, and disposition of samples of usable cannabis;

(4) equipment information detailing the type of equipment used, inspection standards and practices, testing and calibration schedules and records, and standards for cleaning and maintenance of equipment;

(5) reagents, solutions, and reference standards including, but not limited to standards for labeling, storage, expiration, and re-qualification dates and records;

(6) reference standards, acquired or internally produced, including the certificate of analysis;

(7) sample analysis procedures including, but not limited to procedures for the use of only primary or secondary standards for quantitative analyses;

(8) documentation demonstrating that the analytical methods used by the laboratory are appropriate for their intended purpose; that staff is proficient in the process; and that deviations from approved standards of practice do not occur without proper authorization;

(9) standards for data recording, review, storage, and reporting that include, but are not limited to standards to ensure:

(a) that data is recorded in a manner consistent with this rule, and that it is reviewed to verify that applicable standards of practice, equipment calibration, and reference standards were applied before reporting;

(b) that all data, including raw data, documentation, protocols, and reports are retained in accordance with the requirements of this rule; and

(c) that reports are the property of the business or individual who provided the sample, and reports meet the requirements of this rule.

(10) current material safety data sheets for all chemicals used; and

(11) such other materials as the department may require.

E. Proficiency testing and inspection:

(1) A laboratory applicant shall be subject to proficiency testing by the department or its designee prior to approval, and an approved laboratory shall be subject to proficiency testing, at a frequency and at times to be determined by the program manager. A laboratory applicant or approved laboratory shall cooperate with the department or its designee for purposes of conducting proficiency testing. The department or its designee may require submission of cannabis and cannabis-derived product samples from licensed non-profit producers for purposes of proficiency testing.

(2) A laboratory applicant and an approved laboratory shall be subject to inspection(s), at times determined by the program manager, in accordance with the provisions of this rule. The department may require the inspection of premises, equipment, and written materials to determine compliance with this rule, and to determine compliance with the application submissions of the laboratory applicant or approved laboratory, including but not limited to standard operating procedures and standards for testing.

(3) Failure of proficiency testing: If the department determines on the basis of a proficiency test that a laboratory applicant has not satisfactorily identified the presence, quantity, or other relevant factor(s) pertaining to a given analyte, the department may deny the application in whole or in part, require additional tests, or require remedial actions to be taken by the laboratory applicant. If the department determines on the basis of a proficiency test that an approved laboratory has not satisfactorily identified the presence, quantity, or other relevant factor(s) pertaining to a given analyte, the department may withdraw approval of the laboratory in whole or in part, require additional tests, or require remedial actions to be taken by the approved laboratory.

F. Retention and inspection of testing records: An approved laboratory shall maintain all results of laboratory tests conducted on cannabis or cannabis derived products and shall make them available to the program upon the program's request.

G. Identification cards: Identification cards issued by the department are the property of the department and shall be returned to the department upon the termination of the holder's employment with the approved laboratory, upon suspension, or revocation, or upon demand of the department.

H. Term of approval: Department approval of a laboratory for purposes of this rule shall be for a term of one year, and shall expire after that year, or upon closure of the approved laboratory. An approved laboratory shall apply for renewal of approval annually no later than 30 days prior to expiration.

I. Termination: The department may deny, withdraw, or suspend approval of a laboratory in accordance with this rule, upon determination by the department that the laboratory has violated a provision of this rule, upon failure of a proficiency test, upon the refusal of the laboratory to provide requested access to premises or materials, or for upon the failure of a laboratory to comply with any standard, procedure, or protocol developed, submitted, or maintained pursuant to this rule.

[7.34.4.15 NMAC - N, 2/27/2015]

7.34.4.16 DEPARTMENT-APPROVED TESTING LABORATORIES; OPERATIONAL REQUIREMENTS:

A. Receipt of test samples: An approved laboratory may receive test samples of cannabis or cannabis derived products from any licensed producer, qualified patient or primary caregiver.

B. Testing policies: An approved laboratory or laboratory applicant shall establish and implement policies for sample preparation, documentation, and transport, including:

(1) accepted test sample types;

(2) minimum test sample size;

(3) recommended test sample container;

(4) test sample labeling;

(5) transport and storage conditions, such as refrigeration, as appropriate;

(6) other requirements, such as use of preservatives, inert gas, or other measures designed to protect sample integrity; and

(7) creation of chain of custody documentation for each sample.

C. Recording of samples received: An approved laboratory shall:

(1) record the receipt of every test sample received, the record of which shall include:

(a) the name and contact information of the licensed producer that was the source of the sample;

(b) an appropriately specific description of the sample;

(c) the date of receipt of the sample;

(d) a statement of the quantity (weight, volume, number, or other amount) of the sample; and

(e) a unique sample identifier for the sample.

(2) inform each licensed producer or individual who submits a test sample of the policies established in accordance with this section.

D. Sample handling, storage and disposal: An approved laboratory shall establish sample handling procedures for the tracking of test samples through the analytical process (by weight, volume, number, or other appropriate measure) to prevent diversion.

(1) An approved laboratory shall store each test sample under the appropriate conditions to protect the physical and chemical integrity of the sample.

(2) Analyzed test samples consisting of cannabis or cannabis-derived product shall be appropriately segregated, controlled, and held in a controlled access area pending destruction or other disposal.

(3) Any portion of a cannabis or cannabis-derived test sample that is not destroyed during analysis shall be:

(a) returned to the licensed producer who provided the sample; or

(b) destroyed in a manner which prevents unauthorized use; such destruction shall be documented and witnessed by at least two employees, one of whom shall be supervisory or managerial personnel; except that if video surveillance is used, only one employee is required.

E. Local ordinance: An approved laboratory and a laboratory applicant shall comply with all applicable local ordinances, including but not limited to zoning, occupancy, licensing, and building codes.

F. Laboratory premises: An approved laboratory and a laboratory applicant shall maintain the premises of the laboratory in a clean and orderly condition; shall equip the premises with such utensils and equipment as necessary to conduct the operations of the laboratory; and shall ensure adequate space for laboratory operations, sample storage, and document storage.

G. Storage: An approved laboratory and a laboratory applicant shall be equipped with one or more secure, controlled access areas for storage of cannabis and cannabis-derived product test samples, cannabis-derived waste, and reference standards. Access to such storage areas shall be limited by the laboratory to authorized individuals.

H. Equipment:

(1) Equipment used for the analysis of test samples shall be adequately inspected, cleaned, and maintained. Equipment used for the generation or measurement of data shall be adequately tested and calibrated on an appropriate schedule, as applicable.

(2) Laboratory operations shall document procedures setting forth in sufficient detail the methods and schedules to be used in the routine inspection, cleaning, maintenance, testing, and calibration of equipment, and shall specify, as appropriate, remedial action to be taken in the event of failure or malfunction of equipment. The procedures shall designate the personnel responsible for the performance of each operation.

(3) Records shall be maintained of all inspection, maintenance, testing, and calibrating operations. These records shall include the date of the operation, the person who performed it, the written procedure used, and any deviations from the written procedure. Records shall be kept of non-routine repairs performed on equipment as a result of failure and malfunction. Such records shall document the nature of the repair, how and when the need for the repair was discovered, and any remedial action taken in response to the repair.

(4) Computer systems used for the analysis of samples, retention of data, sample tracking, calibration scheduling, management of reference standards, or other critical laboratory management functions shall ensure that electronic records, electronic signatures, and handwritten signatures executed to electronic records are trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

I. Reagents, solutions, and reference standards:

(1) An approved laboratory is authorized to possess reagents, solutions, and reference standards. Such items shall be:

(a) secured in accordance with the approved laboratory's storage policies; labeled to indicate identity, date received or prepared, and expiration or requalification date; and, where applicable, concentration or purity, storage requirements, and date opened;

(b) stored under appropriate conditions to minimize degradation or deterioration of the material; and

(c) used only within the item's expiration or requalification date.

(2) Deteriorated or outdated reagents and solutions shall be properly destroyed.

(3) An approved laboratory may acquire commercial reference standards for cannabinoids and other chemicals or contaminants, for the exclusive purpose of conducting testing for which the laboratory is approved. An approved laboratory may elect to internally produce reference standards. When internally produced, an approved laboratory shall utilize standard analytical techniques to document the purity and concentration of the internally produced reference standards. An approved laboratory is authorized to obtain cannabis or cannabis-derived product from a licensed non-profit producer for this purpose.

(4) An approved laboratory shall obtain or, for internally-produced standards, shall create a certificate of analysis (COA) for each lot of reference standard. Each COA shall be kept on file and the lot number of the reference standard used shall be recorded in the documentation for each analysis, as applicable.

J. Analysis: An approved laboratory shall:

(1) utilize analytical methods that are appropriate for the purpose of testing cannabis and cannabis-derived products;

(2) require analysts to demonstrate proficiency in the performance of the analytical methods used;

(3) maintain written procedures for the analytical method used for the analysis of each test sample, including:

(a) sample preparation;

(b) reagent, solution, and reference standard preparation;

(c) instrument setup, as applicable;

(d) standardization of volumetric reagent solutions, as applicable;

(e) data acquisition; and

(f) calculation of results.

(4) specify, as applicable to each analytical method used, requirements for accuracy, precision, linearity, specificity, limit of detection, limit of quantitation, and other data quality parameters;

(5) ensure that no deviations from approved protocols or standard operating procedures are made during any analytical process without proper authorization and documentation; and

(6) use only primary standards or secondary standards for quantitative analyses.

K. Recording of analytical data:

(1) An approved laboratory shall ensure that all data generated during the testing of a test sample, except data generated by automated data collection systems, is recorded directly, promptly, and legibly in ink. All data shall be annotated with the date of entry and signed or initialed by the person recording the data. Any change in entries shall be made so as not to obscure the original entry, shall indicate the reason for such change, and shall be dated and signed or initialed at the time of the change.

(2) In automated data collection systems, the individual responsible for direct data input shall be identified at the time of data input. Any change in automated data entries shall be made so as not to void or delete the original entry, shall indicate the reason for change, shall be dated, and shall identify the responsible individual.

(3) For each final result reported, an approved laboratory shall verify that:

(a) any calculations or other data processing steps were performed correctly;

(b) the data meet any data quality requirements such as for accuracy, precision, linearity, etc.;

(c) any reference standards used were of the appropriate purity and within their expiration or requalification dates;

(d) any volumetric solutions were properly standardized before use; and

(e) any test or measuring equipment used has been properly tested, verified, and calibrated, and is within its verification or calibration period.

L. Data storage:

(1) An approved laboratory shall ensure that all raw data, documentation, protocols, and final reports associated with analysis of a test sample are retained for two years from the date of the completion of analysis.

(2) An approved laboratory shall maintain the records identified in this section. Such records must be maintained:

(a) in a manner that allows retrieval as needed;

(b) under conditions of storage that minimize deterioration throughout the retention period; and

(c) in a manner that prevents unauthorized alteration.

M. Records maintenance and access: An approved laboratory or laboratory applicant shall designate an individual as responsible for records maintenance. Only authorized personnel may access the maintained records.

N. Data reporting:

(1) Contents of report: A laboratory report of a test conducted at the request of a licensed producer or qualified patient shall contain the following information:

(a) the date of receipt of the test sample;

(b) the description of the type or form of the test sample (leaf, flower, powder, oil, specific edible product, etc.);

(c) the unique sample identifier;

(d) information on whether sampling was performed by the laboratory operation, by the compliant business or individual which submitted the test sample, or by a third-party;

(e) date on which analysis occurred;

(f) the analytical method used, including at a minimum identification of the type of analytical equipment used (e.g., GC, HPLC, UV, etc.);

(g) the analytical results, including units of measure where applicable;

(h) the identity of the supervisory or management personnel who reviewed and verified the data and results and ensured that data quality, calibration, and other applicable requirements were met; and

(i) the name, address, and contact information of the approved laboratory that conducted the test.

(2) The laboratory report shall state that reported analytical results apply only to the test sample received.

O. Destruction of excess cannabis: Unused cannabis, cannabis products, or cannabis-derived product waste that is in the possession of an approved laboratory shall be disposed of by transporting the unused portion to a state or local law enforcement office, or by destruction of the material.

P. Department access to materials and premises: An approved laboratory shall promptly provide the department or the department's designee access to a report of a test, and any underlying data, that is conducted on a sample at the request of a licensed producer or qualified patient. An approved laboratory shall also provide access to the department or the department's designee to laboratory premises, and to any material or information requested by the department, for the purpose of determining compliance with the requirements of this rule.
[7.34.4.16 NMAC - N, 2/27/2015]

7.34.4.17 DEPARTMENT-APPROVED COURIERS; GENERAL PROVISIONS:

A. Approval of couriers: The department may approve a courier for the purpose of transporting usable cannabis from one or more licensed non-profit producers to qualified patients and primary caregivers.

B. Application requirements: An applicant who seeks department approval to operate as a courier shall provide the following materials and information to the department in order to be considered for approval; and an approved courier shall promptly submit revisions in the event that the materials or information changes:

(1) a plan for delivery;

(2) a plan for security, including a description of facilities and containers intended for use in storing and transporting usable cannabis;

(3) a plan for safety, to include at a minimum a description of measures to be taken by the courier and its employees to ensure the safety of qualified patients, primary caregivers, and courier staff;

(4) a description of all vehicles used or intended to be used for the transport of usable cannabis;

(5) a complete list of employees;

(6) clear, legible photocopies of current New Mexico state-issued identification cards of all courier personnel;

(7) completed nationwide and statewide criminal history screening documentation;

(8) a description of the courier's hours of operation;

(9) a description of the locations or type(s) of locations where the courier will offer delivery of usable cannabis;

(10) a description of all licensed non-profit producers for whom the courier will deliver usable cannabis, and copies of all agreements between the courier and licensed non-profit producers for the delivery of usable cannabis;

(11) a description of all fees to be charged by the courier;

(12) protocols for contacting and communicating with qualified patients and primary caregivers regarding deliveries;

(13) training materials for drivers;

(14) confidentiality training materials that address the confidentiality of qualified patient and primary caregiver information;

(15) proof that the non-profit producer is in good standing with the New Mexico taxation and revenue department (TRD);

(16) copies of the applicant's articles of incorporation or organization, as applicable;

(17) copies of the applicant's by-laws, as applicable;

(18) a list of all persons or business entities having direct or indirect authority over the management or policies of the courier, as applicable;

(19) a list of all persons or business entities having any ownership interest in any property utilized by the courier, whether direct or indirect, whether the interest is in land, building(s), or other material;

(20) proof that no buildings to be used by the courier are located within 300 feet of any school, church, or daycare center;

(21) if the courier will base its business at a location that is not owned by the applicant: a written statement from the property owner or landlord of the location that grants to the courier permission to possess cannabis on the premises;

(22) an attestation that the courier will not distribute cannabis within 300 feet of a school, church or daycare center, in accordance with the provisions of this rule; and

(23) an attestation that no firearms will be permitted on any premises or in any vehicle used by the courier; and that no employee will possess a firearm when transporting or distributing cannabis.

C. General requirements: An approved courier shall adhere to each of the following requirements:

(1) a courier may contract with a licensed non-profit producer to deliver usable cannabis from the non-profit producer to a qualified patient or primary caregiver; a courier that provides service to more than one licensed non-profit producer shall offer their service at a uniform price for all non-profit producers for whom they deliver; an approved courier shall not transport a cannabis product that is not individually packaged, or that is not labeled in accordance with this rule;

(2) an approved courier shall not request or receive payment from a qualified patient or primary caregiver; a courier may collect any applicable fee from a licensed non-profit producer;

(3) upon obtaining a package of usable cannabis from a licensed non-profit producer, an approved courier shall hold the package in a secured area or areas that are locked and otherwise resistant to tampering or theft, until the package is delivered to its intended recipient or returned to the licensed non-profit producer;

(4) an approved courier shall not relinquish possession of usable cannabis that is intended for delivery to a qualified patient or primary caregiver unless and until the package of usable cannabis is either successfully delivered or returned to the licensed non-profit producer; for purposes of this section, a package of usable cannabis is successfully delivered only upon the approved courier's verification that an intended recipient has taken actual, physical possession of the package; an approved courier shall not leave a package at any location for any reason, unless the package is successfully delivered to its intended recipient;

(5) an approved courier shall not deliver a package to any person who is not identified by a selling licensed non-profit producer as a purchasing qualified patient or primary caregiver;

(6) at the time of delivery, an approved courier shall verify the recipient's identity by requiring presentation of the qualified patient's or primary caregiver's department-issued medical cannabis identification card and New Mexico-issued photo identification card or a passport; an approved courier shall not deliver usable cannabis to any person whose identity is not verified in accordance with this rule; an approved courier shall document having verified the recipient's identification in accordance with this rule for each transaction;

(7) an approved courier shall not possess usable cannabis for a time period greater than seven days; an approved courier shall return any usable cannabis that is not successfully delivered to its intended recipient to a licensed non-profit producer within this time period;

(8) an approved courier shall not distribute cannabis at locations that are within 300 feet of a school, church, or daycare center; provided that, for purposes of this rule, delivery to the residence of a qualified patient or primary caregiver shall not be deemed "distribution";

(9) an approved courier and its personnel shall at all times take measures to ensure confidentiality and safety in the transport and delivery of usable cannabis to a qualified patient or primary caregiver;

(10) an approved courier shall appropriately train its personnel regarding the confidentiality of information concerning qualified patients and primary caregivers; confidentiality training shall describe confidentiality requirements applicable under both federal and state law; an approved courier shall conduct confidentiality training of its personnel at least once annually, and shall maintain training materials on its premises, and document the training of individual staff; and

(11) personnel of an approved courier shall not possess a firearm while distributing or otherwise possessing cannabis; an approved courier shall not possess or permit the possession of a firearm on any premises, including a building or vehicle, utilized by the courier.

D. Identification cards: The department shall issue an identification card to each authorized employee of an approved courier authorizing that individual to transport cannabis from a non-profit producer to a qualified patient or primary caregiver. An employee of an approved courier shall carry the card at all times that the person transports cannabis, and shall present the card to law enforcement officials upon request. Identification cards

issued by the department are the property of the department and shall be returned to the department upon an approved courier's withdrawal from the program, upon the termination of a card holder's employment with the approved courier, upon suspension or revocation, or upon demand of the department.

E. Term of approval: Department approval of a courier shall be for a term of one year, and shall expire after that year, or upon closure of the courier. A courier shall apply for renewal of approval annually no later than 30 days prior to expiration.

F. Chain of custody: A courier shall adopt, maintain, and enforce chain of custody procedures and documentation requirements to ensure appropriate tracking and inventory of usable cannabis. A courier shall also adopt, maintain, and enforce security requirements to ensure that usable cannabis transported by the courier is secured, and to promote the safety of courier personnel, as well as qualified patients and primary caregivers who receive packages from the courier.

G. Confidentiality: An approved courier may obtain contact information of a purchasing qualified patient or primary caregiver, as permitted by agreement between the courier and a respective licensed non-profit producer, and may utilize such information solely for the purpose of arranging a delivery location and time with the qualified patient or primary caregiver. An approved courier shall not otherwise disseminate, disclose, or use identifying information or contact information concerning a qualified patient or primary caregiver.

[7.34.4.16 NMAC - N, 2/27/2015]

7.34.4.18 QUALIFIED PERSONAL PRODUCTION APPLICATION AND LICENSURE REQUIREMENTS:

A. A qualified patient may apply for a personal production license 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]

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 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 of all registry identification cards and 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]

7.34.4.20 SECURITY REQUIREMENTS FOR LICENSED PRODUCERS: Private non-profit entities licensed to produce medical cannabis shall comply with the following requirements to ensure that production and distribution facilities are located on secure grounds.

A. The non-profit producer shall provide and maintain in each facility a fully operational security alarm system.

B. The non-profit producer shall conduct a monthly maintenance inspection and make all necessary repairs to ensure the proper operation of the alarm system and, in the event of an extended mechanical malfunction that exceeds an eight hour period, provide alternative security that shall include closure of the premises.

C. The non-profit producer shall maintain documentation for a period of at least 24 months of all inspections, servicing, alterations, and upgrades performed on the security alarm system; all documentation shall be made available within 24 hours of a department representative's request; failure to provide equipment maintenance documentation within the 24 hour period shall subject the licensed producer to the sanctions and penalties provided for in this rule; the 24 hour period shall not include holidays and weekends.

[7.34.4.20 NMAC - Rp, 7.34.4.11 NMAC, 2/27/2015]

7.34.4.21 DENIAL OF AN INITIAL PRODUCER LICENSE:

A. Administrative review of license application denials: An applicant whose initial application for a producer license is denied by the medical cannabis program manager or designee may request an administrative review by the administrative review committee. The written notice of denial shall include a statement of the right to request such a review.

B. No administrative review of determinations made by the secretary: An applicant whose initial application for a producer license was for any reason not approved by the secretary (rather than the program manager or designee) shall not be entitled to further review by the department, but may reapply at a later date.

C. Procedure for requesting informal administrative review:

(1) An applicant given notice of an application denial by the medical cannabis program manager or designee may submit a written request for a record review. To be effective, the written request shall:

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

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

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

(d) state the applicant's proposed status as a licensed producer; and

(e) provide a brief narrative rebutting the circumstances of the application denial.

(2) If the applicant wishes to submit additional documentation for consideration, the applicant shall include such additional documentation when submitting the request for administrative review.

D. Administrative review proceeding: The administrative review proceeding shall be a closed proceeding that is limited to an administrative review of written application materials and documents offered to verify eligibility. The administrative review is not an adjudicatory hearing. The administrative review shall be conducted by the administrative review committee. In cases where the administrative review committee finds the need for additional or clarifying information, the review committee shall request that the applicant supply such additional information within the time set forth in the committees' request.

E. Final determination:

(1) Content: The administrative review committee shall render a written decision setting forth the reasons for the decision.

(2) Effect: The decision of the administrative review committee is the final decision of the informal administrative review proceeding.

(3) Notice: A copy of the decision shall be mailed to the applicant.

F. Judicial review: Except as otherwise provided by law, there shall be no right to judicial review of a decision by the program manager or designee, the administrative review committee, or the secretary.
[7.34.4.21 NMAC - Rp, 7.34.4.12 NMAC, 2/27/2015]

7.34.4.22 PROHIBITIONS, RESTRICTIONS, AND LIMITATIONS ON THE PRODUCTION AND DISTRIBUTION OF MEDICAL CANNABIS AND CRIMINAL PENALTIES:

A. Participation in the medical cannabis licensing program by a licensed producer, or the employees or contractors of a licensed producer, does not relieve the producer, employee, or contractor from criminal prosecution or civil penalties for activities not authorized in this rule and the act.

B. Locations of production and distribution: Production of medical cannabis and distribution of medical cannabis to qualified patients or their primary caregivers shall take place at locations (or, with respect to distribution, categories of 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 rule, delivery to the residence of a qualified patient or primary caregiver shall not be deemed "distribution".

C. Fraudulent misrepresentation: Any person who makes a fraudulent representation to a law enforcement officer about the person's participation in the medical cannabis program to avoid arrest or prosecution for a cannabis-related offense is guilty of a petty misdemeanor and shall be sentenced in accordance with the provisions of Section 31-19-1 *et seq.*, NMSA 1978.

D. Unlawful distribution: If a licensed producer or employee of a licensed producer sells, distributes, dispenses, or transfers cannabis to a person not approved by the department pursuant to this rule and the act, or obtains or transports cannabis outside New Mexico in violation of federal law, the licensed producer or employee of the licensed producer shall be subject to arrest, prosecution, and civil or criminal penalties pursuant to state law.

E. Revocation of registry identification card, licensed primary caregiver card, license to produce or distribute: Violation of any provision of this rule may result in disciplinary action, in accordance with this rule.
[7.34.4.22 NMAC - Rp, 7.34.4.14 NMAC, 2/27/2015]

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, and shall be granted immediate access to 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.

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]

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, 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.

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;

(2) five hundred dollars ($500) for the second assessed monetary penalty in a calendar year;

(3) one-thousand dollars ($1,000) for every monetary penalty thereafter assessed in a calendar year.

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; and

(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]

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.

[7.34.4.25 NMAC - Rp, 7.34.4.17 NMAC, 2/27/2015]

7.34.4.26 LICENSED PRODUCER AND PRODUCER-APPLICANT CONFIDENTIALITY:

A. The department shall maintain a confidential file containing the names, addresses, and telephone numbers of the persons or entities who have either applied for or received a license for the purpose of producing and distributing cannabis for medical use. Individual names of producers and producer-applicants shall be confidential and not subject to disclosure, except:

(1) to authorized employees or agents of the department as necessary to perform the duties of the department pursuant to the provisions of this rule and the act;

(2) to state or local regulatory agencies and entities, for purposes related to those agencies' or entities' duties under applicable law;

(3) to authorized employees of state or local law enforcement agencies, but only for the purpose of verifying that a person is lawfully in possession of the license to produce, or as otherwise expressly permitted in this rule; and

(4) as provided in the federal Health Insurance Portability and Accountability Act of 1996.

B. A pending application for licensure as a non-profit producer shall be confidential and not subject to disclosure.

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

7.34.4.27 STORAGE AND DISPOSAL OF CANNABIS BY LICENSED PRODUCERS:

A. Storage: Medical cannabis, unused cannabis products, and cannabis-derived product waste shall be stored by a licensed producer in a manner that discourages diversion or theft, until such time as the material is transferred, disposed of, or destroyed in accordance with this rule.

B. Disposal by personal production license holders: Unused cannabis, cannabis products, or cannabis-derived product waste that is in the possession of a qualified patient who holds a personal production license shall be disposed of by transporting the unused portion to a state or local law enforcement office, or by destruction of the material.

[7.34.4.27 NMAC - Rp, 7.34.4.19 NMAC, 2/27/2015]

7.34.4.28 ASSESSMENT REPORT: The department shall evaluate the implementation of the Lynn and Erin Compassionate Use Act and regulations issued pursuant to that act and provide a report to the secretary of the department within one year of the effective date of this regulation. In performing its evaluation, the department shall focus on whether the needs of qualified patients are being met by the department's administration of the act and whether there is a demonstrable need for a state run production and distribution facility. The department's assessment report shall be issued every two years, shall be a public document, and must contain de-identified data upon which the assessment is based.

[7.34.4.28 NMAC - Rp, 7.34.4.20 NMAC, 2/27/2015]

7.34.4.29 SEVERABILITY: If any part or application of these rules is held to be invalid, the remainder or its application to other situations or persons shall not be affected. Any section of these rules legally severed shall not interfere with the remaining protections provided by these rules and the act.

[7.34.4.29 NMAC - Rp, 7.34.4.21 NMAC, 2/27/2015]

HISTORY OF 7.34.4 NMAC:

History of Repealed Material:

7.34.4 NMAC, Licensing Requirements for Producers, Production Facilities and Distribution (filed 12/01/2008) repealed 12/30/2010.

7.34.4 NMAC, Licensing Requirements for Producers, Production Facilities and Distribution (filed 12/16/2010) repealed 2/27/2015.

NMAC History:

7.34.4 NMAC, Licensing Requirements for Producers, Production Facilities and Distribution (filed 12/01/2008) was replaced by 7.34.4 NMAC, Licensing Requirements for Producers, Production Facilities and Distribution, effective 12/30/2010.

7.34.4 NMAC, Licensing Requirements for Producers, Production Facilities and Distribution (filed 12/16/2010) was replaced by 7.34.4 NMAC, Licensing Requirements for Producers, Couriers, Manufacturers and Laboratories, effective 2/27/2015.