

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 provision, delivery to the residence of a qualified patient or primary caregiver shall not be deemed "distribution". A licensed non-profit producer may, consistent with this rule, and with the consent of a purchasing qualified patient or primary caregiver, utilize an approved courier to transport usable cannabis to a qualified patient or primary caregiver, and may for this purpose share with an approved courier the contact information of the purchasing qualified patient or primary caregiver. **A licensed non-profit producer may, consistent with this rule, also utilize an approved courier to transport usable cannabis to another non-profit producer, to an approved laboratory, and to an approved manufacturer.** A licensed non-profit producer shall not identify any person as an intended recipient of usable cannabis who is not either a qualified patient or a primary caregiver, **an approved courier, an approved manufacturer, or an approved laboratory.**

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.

7.34.4.9 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 **in accordance with this rule** 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.~~

(45) 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.

(56) 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.

7.34.4.14 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. pesticide(s) used in the production of the cannabis or cannabis-derived product;

H.G. instructions for use;

L.H. warnings for use;

J.I. instructions for appropriate storage;

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

L.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;

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

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

7.34.4.15 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;
- (45) quantity of THC and CBD; and
- (56) 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~~ retain all results of laboratory tests conducted on cannabis or cannabis derived products for a period of at least two years 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.

7.34.4.17 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, other non-profit producers, approved manufacturers and approved laboratories.

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 provision~~, 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.

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

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

L. Local ordinance: A licensed non-profit producer shall comply with all applicable local ordinances, including but not limited to zoning, occupancy, licensing, and building codes.

7.34.4.26 LICENSED PRODUCER PERSONAL PRODUCTION LICENSE AND PRODUCER-APPLICANT CONFIDENTIALITY:

A. Personal production license holders and applicants: 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 personal production license (PPL) for the purpose of producing and distributing cannabis for medical use. Individual names of PPL producers and PPL 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)~~ (2) 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)~~ (3) as provided in the federal Health Insurance Portability and Accountability Act of 1996.

B. Non-profit producer applicants: A pending application for initial licensure as a non-profit producer shall be confidential and not subject to disclosure while the applications period is open for the receipt of applications. Pending non-profit producer applications for initial licensure shall cease to be confidential upon the closure of the applications period.

7.34.3.8 QUALIFYING DEBILITATING MEDICAL CONDITIONS:

A. Statutorily-approved conditions: As of the date of promulgation of this rule, specific qualifying debilitating medical conditions, diseases, and treatments (“qualifying conditions”) identified in the Lynn and Erin Compassionate Use Act, Section 26-2B-3(B) NMSA 1978, include:

- (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; and

(7) admission into hospice care in accordance with rules promulgated by the department.

B. Department-approved conditions: The department finds that the following additional qualifying conditions result in pain, suffering, or debility for which there is credible evidence that the medical use of cannabis could be of benefit, through the alleviation of symptoms, and the department accordingly approves these conditions as qualifying debilitating medical conditions for the participation of a qualified patient or primary caregiver in the medical cannabis program. The department-approved conditions include:

(1) severe chronic pain:

(a) objective proof of the etiology of the severe chronic pain shall be included in the application; and

(b) a practitioner familiar with the patient's chronic pain shall provide written certification that the patient has an unremitting severe chronic pain condition; ~~for an initial patient application, this certification shall be made by a specialist with expertise in pain management or a specialist with expertise in the disease process that is causing the pain; for all subsequent patient applications, this certification may be made by a primary care provider.~~

(2) painful peripheral neuropathy: application to the medical cannabis program shall be accompanied by medical records that confirm the objective presence of painful peripheral neuropathy ~~that has been refractory to other treatments;~~

(3) intractable nausea/vomiting;

(4) severe anorexia/cachexia;

(5) hepatitis C infection currently receiving antiviral treatment: the written certification shall attest:

(a) that the hepatitis C infection is currently being treated with antiviral drugs; and

(b) to the anticipated duration of the hepatitis C antiviral treatment.

(6) Crohn's disease;

(7) post-traumatic stress disorder (PTSD): each individual applying to the program for enrollment shall submit medical records that confirm ~~the a~~ diagnosis of PTSD ~~based upon the evaluation of a psychiatrist, psychiatric nurse practitioner, or prescribing psychologist, and~~ meeting the diagnostic criteria of the current *diagnostic and statistical manual of mental disorders*;

(8) inflammatory autoimmune-mediated arthritis: each individual applying to the program for enrollment shall submit medical records that confirm the diagnosis of inflammatory autoimmune-mediated arthritis ~~based upon the evaluation of a rheumatologist who is board certified in rheumatology by the American board of internal medicine;~~

(9) amyotrophic lateral sclerosis (Lou Gehrig's disease);

(10) inclusion body myositis;

(11) spasmodic torticollis (cervical dystonia);

(12) Parkinson's disease;

(13) Huntington's disease;

(14) ulcerative colitis; and

(15) such other conditions as the secretary may approve.

C. Additional application requirements for department-approved conditions: A patient ~~applying on the basis of having a department approved qualifying condition~~ shall submit written certification from the patient's practitioner which shall attest:

(1) to the diagnosis of the medical condition;

(2) that the condition is debilitating; ~~and~~

(3) ~~that standard treatments have failed to bring adequate relief, unless the practitioner determines that standard treatments would be harmful to the patient's health; and~~

~~(4) —~~that potential risks and benefits of the use of medical cannabis for the condition have been discussed with the patient, in accordance with this rule; a patient who applies on the basis of having a department-approved condition may also be required to satisfy additional eligibility criteria, as specified in this rule.

D. Modification or removal of department-approved conditions: The secretary may remove or modify a department-approved condition only if the secretary determines, on the basis of substantial credible medical and scientific evidence, and after an opportunity for review of the proposed removal or modification by the medical advisory board, that the use of cannabis by patients who have the approved condition would more likely than not result in substantial harm to the patients' health.

7.34.3.16 DISCIPLINARY ACTIONS AND APPEAL PROCESS:

A. Grounds for disciplinary action: Disciplinary action may be taken against a qualified patient, patient-applicant, primary caregiver, or primary caregiver-applicant. Disciplinary action may include revocation, suspension, or denial, summary suspension, summary revocation, 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 monitoring visit;
- (7) diversion of cannabis or a cannabis-derived product, as determined by the department;
- (8) threatening or harming a patient, a medical practitioner, or an employee of the department;
- (9) for primary caregivers: any determination by the primary caregiver's licensing body that the primary caregiver has engaged in unprofessional or dishonorable conduct;
- (10) for primary caregivers: conviction of the primary caregiver of any of the disqualifying convictions identified by department rule;
- (101) for patients: failure of the patient to satisfy any criterion identified as a prerequisite to eligibility for a condition approved by the department;
- (112) for patients: if a certifying provider of the patient determines that the use of cannabis by the patient would more likely than not be detrimental to the patient's health; and
- (123) any other basis identified in this rule.

B. Request for hearing: A qualified patient or primary caregiver who is the subject of disciplinary action, or an applicant who has received a notice of contemplated action to deny their application for any reason other than failure to submit a completed application or failure to meet a submittal requirement of this rule, may request a hearing in writing. 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 numbers; and
- (3) include a statement of the issues that the appellant considers relevant to the review of the action.

C. Hearing process:

- (1) All formal adjudicatory hearings held pursuant to this regulation shall be conducted by a hearing examiner appointed by the secretary.
- (2) Hearings shall be conducted in Santa Fe, New Mexico, or, with the consent of the parties, at another location.
- (3) Due to federal and state laws regarding the confidentiality of protected health information, all hearings held pursuant to this section shall be closed to the public.
- (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.

D. Scheduling: The department shall schedule and hold the hearing no later than 60 calendar days from the date the department receives the appellant's request for hearing. The hearing examiner may extend the 60 day time period for good cause shown, or the parties may extend that period by mutual agreement. The department shall issue notice of the hearing, which shall include:

- (1) a statement of the time, place, and nature of the hearing;
- (2) a statement of the legal authority and jurisdiction under which the hearing is to be held;
- (3) a short and plain statement of the subject of the hearing.

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

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

- (1) all pleadings, motions, and rulings;
- (2) evidence and briefs received or considered;
- (3) a statement of any 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.

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

H. 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.

I. Conduct of proceeding: Unless the hearing examiner determines a different procedure to be appropriate, the hearing shall be conducted as follows:

- (1) the appellant may present an opening statement and the department may present an opening statement or reserve the statement until presentation of its case;
- (2) upon conclusion of any opening statements, the appellant shall present his or her case;
- (3) upon the conclusion of the appellant's case, the department shall present its case;
- (4) upon conclusion of either party's case, the opposing party may present rebuttal evidence;

and

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

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

K. 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.

L. 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) failure of an appellant to provide their correct telephone number or failure to be available at the commencement of the hearing shall be treated as a failure to appear and shall constitute a default;
- (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.

M. 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, reversing, or modifying the 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 made a part of the patient or primary caregiver's file with the medical cannabis program.

7.34.2.7 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 of a producer’s license, in accordance with department rules. The administrative review committee shall consist of the chief medical officer of the department (or that person’s designee); a deputy secretary of the department (or that person’s designee), and the chief nursing officer of the department (or that person’s designee).

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

E. “Advisory board” means the medical cannabis advisory board consisting of eight 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 no greater than five pounds that is harvested during a specified time period from a specified cultivation area, and with regard to concentrated and cannabis-derived product, means an identified quantity that is uniform, that is intended to meet specifications for identity, strength, and composition, and that is manufactured, packaged, and labeled during a specified time period according to a single manufacturing, packaging, and labeling protocol.

I. “Cannabidiol (“CBD”)” is a cannabinoid and the primary non-psychoactive ingredient found in cannabis.

J. “Cannabis” means all parts of the plant, cannabis sativa, and cannabis indica, whether growing or not and the resin extracted from any part of the plant.

K. “Cannabis-derived product” means a product, other than cannabis itself, which contains or is derived from cannabis, not including hemp.

L. “Concentrated cannabis-derived product (“concentrate”)” means a cannabis-derived product that is manufactured by a mechanical or chemical process that separates any cannabinoid from the cannabis plant, and that contains (or that is intended to contain at the time of sale or distribution) no less than thirty-percent (30%) THC by weight.

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

N. “Debilitating medical condition” means:

- (1) cancer;
- (2) glaucoma;
- (3) multiple sclerosis;
- (4) damage to the nervous tissue of the spinal cord, with objective neurological indication of intractable spasticity;
- (5) epilepsy;
- (6) positive status for human immunodeficiency virus or acquired immune deficiency syndrome;
- (7) admission into hospice care in accordance with rules promulgated by the department; 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.

7.34.3.7 DEFINITIONS:

A. “**Act**” means the Lynn and Erin Compassionate Use Act, Sections 26-2B-1 through 26-2B-7 NMSA 1978.

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 ~~of a producer’s license~~, in accordance with department rules. The administrative review committee shall consist of the chief medical officer of the department (or that person’s designee); a deputy secretary of the department (or that person’s designee), and the chief nursing officer of the department (or that person’s designee).

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

E. “**Advisory board**” means the medical cannabis advisory board consisting of eight 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 **no greater than five pounds that is** harvested during a specified time period from a specified cultivation area, and with regard to concentrated and cannabis-derived product, means an identified quantity that is uniform, that is intended to meet specifications for identity, strength, and composition, and that is manufactured, packaged, and labeled during a specified time period according to a single manufacturing, packaging, and labeling protocol.

I. “**Cannabidiol (“CBD”)**” is a cannabinoid and the primary non-psychoactive ingredient found in cannabis.

J. “**Cannabis**” means all parts of the plant, cannabis sativa, and cannabis indica, whether growing or not and the resin extracted from any part of the plant.

K. “**Cannabis-derived product**” means a product, other than cannabis itself, which contains or is derived from cannabis, not including hemp.

L. “**Concentrated cannabis-derived product (“concentrate”)**” means a cannabis-derived product that is manufactured by a mechanical or chemical process that separates any cannabinoid from the cannabis plant, and that contains (or that is intended to contain at the time of sale or distribution) no less than thirty-percent (30%) THC by weight.

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

N. “**Debilitating medical condition**” means:

- (1) cancer;
- (2) glaucoma;
- (3) multiple sclerosis;
- (4) damage to the nervous tissue of the spinal cord, with objective neurological indication of intractable spasticity;
- (5) epilepsy;
- (6) positive status for human immunodeficiency virus or acquired immune deficiency syndrome;
- (7) admission into hospice care in accordance with rules promulgated by the department; 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.
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- 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.
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- 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.
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7.34.4.7 DEFINITIONS:

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