TITLE 7 HEALTH
CHAPTER 34 MEDICAL USE OF CANNABIS
PART 4 LICENSING REQUIREMENTS FOR PRODUCERS, PRODUCTION FACILITIES AND DISTRIBUTION

7.34.4.1 ISSUING AGENCY: New Mexico Department of Health, Public Health Division.
[7.34.4.1 NMAC - Rp, 7.34.4.1 NMAC, 12/30/2010]

7.34.4.2 SCOPE: This rule applies to all licensed producers of medical use cannabis, defined in Section 26-2B-3 (D) NMSA 1978 as "any person or association of persons within New Mexico that the department determines to be qualified to produce, possess, distribute and dispense cannabis pursuant to the Lynn and Erin Compassionate Use Act and that is licensed by the department." All requirements contained herein are necessary prerequisites to the state's ability to distinguish between authorized use under this act and unauthorized use under the state's criminal laws.
[7.34.4.2 NMAC - Rp, 7.34.4.2 NMAC, 12/30/2010]

7.34.4.3 STATUTORY AUTHORITY: The requirements set forth herein are promulgated by the secretary of the department of health, pursuant to the general authority granted under Section 9-7-6 (E) NMSA 1978, as amended, and the authority granted under Sections 24-1-2(D), 24-1-3(I) and 24-1-5, NMSA 1978, of the Public Health Act, as amended, Section 53-8-1 et seq. NMSA 1978, and the Lynn and Erin Compassionate Use Act. Although federal law currently prohibits any use of cannabis, the laws of Alaska, California, Colorado, the District of Columbia, Hawaii, Maine, Michigan, Montana, Nevada, New Jersey, Oregon, Rhode Island, Vermont, and Washington permit the medical use and cultivation of cannabis. New Mexico joins this effort to provide for the health and welfare of its citizens. New Mexico adopts these regulations to accomplish the purpose of the Lynn and Erin Compassionate Use Act as stated in Section 26-2B-2, NMSA 1978, "to allow for the beneficial use of medical cannabis in a regulated system for alleviating symptoms caused by debilitating medical conditions and their medical treatments," while at the same time ensuring proper enforcement of any criminal laws for behavior that has been deemed illicit by the state.
[7.34.4.3 NMAC - Rp, 7.34.4.3 NMAC, 12/30/2010]

7.34.4.4 DURATION: Permanent.
[7.34.4.4 NMAC - Rp, 7.34.4.4 NMAC, 12/30/2010]

7.34.4.5 EFFECTIVE DATE: December 30, 2010, unless a later date is cited at the end of a section.
[7.34.4.5 NMAC - Rp, 7.34.4.5 NMAC, 12/30/2010]

7.34.4.6 OBJECTIVE: Ensuring the safe production, distribution and dispensing of cannabis for the sole purpose of medical use for alleviating symptoms caused by debilitating medical conditions in a regulated system.
[7.34.4.6 NMAC - Rp, 7.34.4.6 NMAC, 12/30/2010]

7.34.4.7 DEFINITIONS:

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

B. "Administrative review committee" means an intra-department committee that reviews qualified patient or primary caregiver application denials, licensed producer denials, or the imposition of a summary suspension. The administrative review committee shall consist of the medical director for the department's public health division (or that person's designee); the director of the public health division (or that's person's designee); and the chief of the infectious disease bureau of the department's public health division (or that person's designee).

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

D. "Adequate supply" means an amount of cannabis, derived solely from an intrastate source and in a form approved by the department, 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 (3) months. An adequate supply shall not exceed six (6) ounces of useable cannabis, and with a personal production license only,

four (4) mature plants and twelve (12) seedlings, or a three (3) month supply of topical treatment. A qualified patient and primary caregiver may also possess cannabis seeds.

E. "Adverse action" includes the denial of any application, immediate revocation of the qualified patient or primary caregiver's registry identification card, licensed producer revocation, referral to state or local law enforcement and loss of all lawful privileges under the act.

F. "Advisory board" means the medical cannabis advisory board consisting of eight (8) practitioners representing the fields of neurology, pain management, medical oncology, psychiatry, infectious disease, family medicine and gynecology.

G. "Applicant" means any person applying to participate in the medical use of cannabis program as a qualified patient, primary caregiver or licensed producer.

H. "Cannabis" means all parts of the plant cannabis sativa and cannabis indica, whether growing or not, the resin extracted from any part of the plant, and every compound, manufacture, salt, derivative, mixture, or preparation of the plant or its resin.

I. "Consent to release of medical information form" means a signed qualified patient or primary caregiver authorization form to release specific medical information relating to the use of cannabis.

J. "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.

K. "Deficiency" means a violation of or failure to comply with a provision of these requirements.

L. "Department" means the department of health or its agent.

M. "Division" means the public health division of the department of health.

N. "Facility" means any building or grounds licensed for the production, possession and distribution of cannabis in any form.

O. "Intrastate" means existing or occurring within the state boundaries of New Mexico.

P. "License" means the document issued by the department granting the legal right to produce and distribute medical cannabis for a specified period of time.

Q. "Licensed producer" means a person or entity licensed to produce medical cannabis.

R. "Licensure" means the process by which the department grants permission to an applicant to produce or possess cannabis.

S. "Mature plant" means a harvestable female cannabis plant that is flowering.

T. "Medical cannabis program" means the administrative body of the New Mexico public health division charged with the management of the medical cannabis program, to include issuance of registry identification cards, licensing of producers and distribution systems, administration of public hearings and administration of informal administrative reviews.

U. "Medical cannabis program manager" means the administrator of the New Mexico department of health, public health division medical cannabis program who holds that title.

V. "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.

W. "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.

X. "Minor" means an individual less than eighteen (18) years of age.

Y. "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 into the human body.

Z. "Participant enrollment form" means the registry identification card application form for adult qualified patient applicants provided by the medical cannabis program.

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

BB. "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.

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

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

EE. "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).

FF. "Primary caregiver" means a resident of New Mexico who is at least eighteen (18) years of age and who has been designated by the qualified patient or 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, NMSA 1978, Section 26-2B-1 *et seq*.

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

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

II. "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.

JJ. "Registry identification card" means a document issued 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.

KK. "Representative" means an individual designated as the petitioner's agent, guardian, surrogate, or other legally appointed or authorized health care decision maker pursuant to the Uniform Health Care Decisions Act, Sections 24-7A-1 *et seq*. (NMSA 2007).

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

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

NN. "Security alarm system" means any device or series of devices, 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 an unauthorized intrusion.

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

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

QQ. "Submission date" means the date of submission of the last item in an application, petition or proposal.

RR. "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.

SS. "Topical treatment" means a transcutaneous therapeutic cannabis extract formulation.

TT. "Usable cannabis" means the dried leaves and flowers of the female cananbis plant and any mixture or preparation thereof, including ointments, but does not include the seedlings, seeds, stalks, or roots of the plant.

[7.34.4.7 NMAC - Rp, 7.34.4.7 NMAC, 12/30/2010]

7.34.4.8 PRODUCER LICENSING; GENERAL PROVISIONS:

A. The department may license two classes of producers.

(1) A qualified patient who shall produce no more than an adequate supply of cannabis for the qualified patient's personal use only; and who may obtain useable cannabis, seeds or plants from licensed non-profit producers.

(2) A non-profit private entity that operates a facility and, at any one time, is limited to a total of one-hundred and fifty (150) mature plants and seedlings and an inventory of usable cannabis and seeds that reflects current patient needs, and that shall sell cannabis with a consistent unit price, without volume discounts. A licensed non-profit producer may obtain plants, seeds and useable cannabis from other licensed non-profit producers.

B. Processing of production applications.

(1) The issuance of an application form 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 private entity whose application for licensure is not approved by the secretary shall not be entitled to further administrative review.

C. 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 plan to ensure purity, consistency of dose, and the various forms of applications to be provided; i.e., topical, oral, tinctures, etc.;

(4) the applicant's skill and knowledge of organic growing methods to ensure a safe product;

(5) the quality of the security plan proposed, including location, security devices employed and staffing;

(6) the quality assurance plans in place, including provision for periodic testing;

(7) the experience and expertise of the non-profit board members; and

(8) other relevant factors.

D. Production and distribution of medical cannabis by a licensed non-profit private entity. Production and distribution of medical cannabis by a non-profit private entity to a qualified patient or primary caregiver shall take place at locations described in the non-profit entity's production and distribution plan approved by the department, and shall not take place at locations that are within three hundred (300) feet of any school, church or daycare center.

E. 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.

F. 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.

G. Non-profit private entity criminal history screening requirements. All persons associated with a non-profit private entity production facility shall consent to and undergo a nationwide and statewide criminal history screening background check. This includes board members, persons having direct or indirect authority over management or policies, and employees.

(1) Criminal history screening fees. All applicable fees associated with the nationwide and statewide criminal history screening background checks shall be paid by the individual or the non-profit private entity.

(2) Disqualifying convictions. Individuals convicted of a felony violation of Section 30-31-20, 30-31-21, or 30-31-22 NMSA 1978, or a violation of any equivalent federal statute or equivalent statute from any other jurisdiction, shall be prohibited from participating or being associated with a production facility licensed under this

rule. If an individual has been convicted of a felony violation of Section 30-31-1 *et seq*. NMSA 1978 other than Sections 30-31-20 through 30-31-22, 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 (5) 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 or working for the entity. An individual who is disqualified shall be notified of his or her disqualification. If the individual has been convicted of more than one (1) felony violation of Section 30-31-1 et seq. NMSA 1978 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 production facility licensed under this rule. Any violation of this subsection shall result in the immediate revocation of any privilege granted under this rule and the act.

H. Board membership requirements for private entities. The board of directors for a private non-profit applicant or licensee shall include at a minimum five (5) voting members, including one (1) medical provider limited to a physician (MD or DO), a registered nurse, nurse practitioner, licensed practical nurse or physician assistant, and three (3) 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 private entity shall be residents of New Mexico.

(3) Beginning July 1, 2011 and continuing thereafter, no member of the non-profit producer's board of directors may serve on more than one single board of directors for licensed non-profit producers.

I. Private entity policies and procedures: The private non-profit entity 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 identifiable photocopies of the registry identification card of every qualified patient or primary caregiver served by the private entity;

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

(3) 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 confidentiality laws;

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

(5) 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;

(6) 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;

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

(a) safety and security procedures;

(b) personal safety; and

(c) crime prevention techniques;

(8) 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; and

(9) a written policy regarding the right of the private entity to refuse service.

J. Retention of training documentation: A private non-profit entity shall maintain documentation of an employee's training for a period of at least six (6) months after termination of an employee's employment. Employee training documentation shall be made available within twenty-four (24) hours of a department representative's request; the twenty-four (24) hour period shall exclude holidays and weekends.

K. Licensure periods:

(1) Licensure period for private entities. The licensure period of a private entity shall be from January 1st (or the date of approval of the licensure application, if later) through December 31st of a given year. A license that was issued prior to the promulgation of this provision that is scheduled to expire before December 31, 2011 shall be extended to that date.

(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.

L. 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 thirty (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 the private non-profit entity, change of ownership, private entity name, capacity or any physical modification or addition to the facility; and

(3) substantial change to a private entity's production and distribution plan, including any change to the type(s) of products produced, the private entity's method(s) of distribution, and security plan.

M. Application for renewal of an annual production license.

(1) Deadline for private entities. Each licensed producer shall apply for renewal of its annual license no later than December 1st of each year by submitting a renewal application to the department. The department shall provide the renewal application requirements no later than October 1st of each year.

(2) Deadline for qualified patients. Each patient licensed for a personal production license 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 shall submit:

(a) an application for renewal of license; and

(b) a non-refundable thirty-dollar ($30) application fee, except 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.

(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.

N. 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 licensing authority 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 (2) or more corporations merge and the originally licensed corporation survives.

(3) Management agreements are generally not considered a change in ownership if the licensed producer continues to retain ultimate authority for the operation of the facility. However, if the ultimate authority is surrendered and transferred from the licensed producer to a new manager, then a change of ownership has occurred.

O. 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 shall notify the licensing authority no later than thirty (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 must be turned over to local law enforcement, destroyed by the producer, or 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.

P. 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.

Q. Fees applicable to applicants and licensees:

(1) Private non-profit application fee: A non-profit producer shall submit with its initial application a non-refundable application fee of one thousand dollars ($1,000).

(2) Private non-profit renewal fee: A non-profit private entity that has been licensed for more than six months shall additionally submit to the medical cannabis program a non-refundable renewal fee no later than December 1st of each year of:

(a) five-thousand dollars ($5,000) if the producer has been licensed for less than one year but more than six months;

(b) ten-thousand dollars ($10,000) if the producer has been licensed for more than one year;

(c) twenty-thousand dollars ($20,000) if the producer has been licensed for more than two years;

(d) thirty-thousand dollars ($30,000) if the producer has been licensed for more than three years.

(3) Qualified patient producer fees: A qualified patient shall submit with each initial application and renewal application for personal production licensure a fee of thirty dollars ($30), unless the fee is waived on 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.

(4) 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 harm reduction program of the department.

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

(1) the department or its designee shall maintain chain of custody documentation for any medical cannabis samples taken;

(2) a written receipt shall be given to the producer for all testing samples;

(3) all testing samples shall be placed into a sealed container and clearly labeled;

(4) all testing samples shall be tested by DOH or a designated testing facility;

(5) no more than eight (8) grams of medical cannabis shall be gathered for testing purposes from a non-profit medical cannabis producer on any single occasion;

(6) no more than one (1) gram of medical cannabis shall be gathered for testing purposes from a patient who holds a personal production license on any single occasion.

[7.34.4.8 NMAC - Rp, 7.34.4.8 NMAC, 12/30/2010]

7.34.4.9 QUALIFIED PERSONAL PRODUCTION APPLICATION REQUIREMENTS:

A. A qualified patient may apply for a personal production license to produce medical cannabis solely for the qualified patient's own use.

B. A qualified patient may obtain no more than one personal production license, which license may be issued for production to occur in no more than one single location, which shall be either the patient's primary residence, or other property owned by the patient.

C. Only one personal production license may be issued for a given location, absent proof that more than one registered patient currently resides at the location. Multiple personal production licenses may not be issued for non-residential locations.

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

(1) appropriate non-refundable fee Paragraph (3) of Subsection Q of 7.34.4.8 NMAC;

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

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

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

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

[7.34.4.9 NMAC - N, 12/30/2010]

7.34.4.10 NON-PROFIT PRIVATE ENTITY PRODUCTION APPLICATION REQUIREMENTS: A private non-profit entity shall provide the following in order to be considered for a license to produce medical cannabis.

A. Organizational information and materials: A private non-profit entity shall submit to the department:

(1) proof that the private entity is a non-profit corporation pursuant to Section 53-8-1 *et seq*. NMSA 1978;

(2) copies of the entity's articles of incorporation;

(3) copies of the entity's by-laws;

(4) verification that the board of directors of the non-profit includes, at a minimum, five (5) voting members, including one (1) medical provider limited to a physician (MD or OD), a registered nurse, nurse practitioner, licensed practical nurse or physician assistant, and three (3) patients currently qualified under the Lynn and Erin Compassionate Use Act, NMSA 1978, Section 26-2B-1 *et seq.*;

(5) a list of all persons or business entities having direct or indirect authority over the management or policies of the facility;

(6) a list of all persons or business entities having five percent or more ownership in the facility, whether direct or indirect and whether the interest is in land, building, or other material, including owners of any business entity which owns all or part of the land or building;

(7) the identities of all creditors holding a security interest in the premises of the private entity, if any; and

(8) a brief business plan showing how the private entity will fund operations during the first two years of licensing, including funding sources.

B. Production and distribution information and materials: A private non-profit entity shall submit to the department:

(1) an acknowledgement that production, at any time, shall not exceed a total of one-hundred and fifty (150) mature plants, seedlings, cuttings, and clones, as well as an inventory of usable cannabis that reflects current patient needs;

(2) 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, and that includes a clear identifiable photocopy of all qualified patient's or the primary caregiver's registry identification card served by the private entity;

(3) a complete written description of the means that the private non-profit shall employ to safely dispense the cannabis to qualified patients or the qualified patient's primary caregivers;

(4) a description and sample of the packaging of the useable cannabis that the private non-profit entity shall utilize, including a label that shall contain the name of the strain, batch, quantity and a statement that the product is for medical use and not for resale; and

(5) a description of the testing procedures the private entity shall use to determine the quality of medical cannabis produced or distributed.

C. Facility information: A private non-profit entity shall submit to the department:

(1) a description of the facility that shall be used in the production of cannabis;

(2) proof that the facility is not within three hundred (300) feet of any school, church or daycare center; and

(3) a description of the device or series of devices that shall be used to provide security.

D. Educational methods and materials: A private non-profit entity 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 useable cannabis provided by the private entity;

(4) a description of safe smoking techniques that shall be provided to qualified patients; and

(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.

E. Sales records: A private non-profit entity shall submit to the department a sample of the private entity's sales record form(s), which shall identify (among other items) the name of the purchaser, the date of the sale, and the quantity and price of medical cannabis sold.

F. Policies and procedures: A private non-profit entity shall submit to the department copies of policies and procedures developed, implemented and maintained on the premises of the private entity's facility.

G. Personnel records: A private non-profit entity shall submit to the department:

(1) nationwide and statewide criminal history screening documentation for all individuals associated with the private entity's production facility, to include board members, persons having direct or indirect authority over management or policies, employees, and volunteers;

(2) samples of the personnel records retained by the private entity for each employee as required by this rule, including:

(a) a sample application for employment;

(b) sample record of any disciplinary action taken;

(c) a sample written job descriptions or employment contracts developed for all employee positions, to include duties, authority, responsibilities, qualifications and supervision;

(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 HIPAA;

(b) professional conduct and ethics;

(c) informational developments in the field of medical use of cannabis; and

(d) 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; and

(4) proof of HIPAA certification for all individuals associated with a private entity production facility, including all board members, persons having direct or indirect authority over management or policies, employees, and volunteers.

H. Other materials: A private non-profit entity shall submit to the department such other information as the private entity wishes to provide or such information as the department may reasonably request.
[7.34.4.10 NMAC - N, 12/30/2010]

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

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

B. The licensed private non-profit entity shall conduct a monthly maintenance inspection and make all necessary repairs to ensure the proper operation of the alarm system and, in the event of an extended mechanical malfunction that exceeds an eight (8) hour period, provide alternative security that shall include closure of the premises.

C. The licensed private non-profit entity shall maintain documentation for a period of at least twenty-four (24) months of all inspections, servicing, alterations and upgrades performed on the security alarm system; all documentation shall be made available within twenty-four (24) hours of a department representative's request; failure to provide equipment maintenance documentation within the twenty-four (24) hour period shall subject the licensed producer to the sanctions and penalties provided for in this rule; the twenty-four (24) hour period shall not include holidays and weekends.
[7.34.4.11 NMAC - Rp, 7.34.4.9 NMAC, 12/30/2010]

7.34.4.12 DENIAL OF AN INITIAL PRODUCER LICENSE:

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

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

C. Procedure for requesting informal administrative review:

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

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

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

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

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

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

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

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

E. Final determination:

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

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

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

F. Judicial review: Except as otherwise provided by law, there shall be no right to judicial review of a decision by the program manager or designee, the administrative review committee, or the secretary.

[7.34.4.12 NMAC - Rp, 7.34.4.10 NMAC, 12/30/2010]

7.34.4.13 PARENTAL RESPONSIBILITY ACT: The failure to comply with a judgment or order for child support, or subpoena or warrants relating to paternity or child support proceedings, is grounds for the denial, suspension or revocation of a private entity's license to produce medical cannabis in accordance with Section 40-5A-6, NMSA 1978, of the Parental Responsibility Act.

[7.34.4.13 NMAC - Rp, 7.34.4.11 NMAC, 12/30/2010]

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

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

B. Locations of production and distribution: Production of medical cannabis and distribution of medical cannabis to qualified patients or their primary caregivers shall take place at locations (or, with respect to distribution, categories of locations) described in the non-profit entity's production and distribution plan approved by the department, and shall not take place at locations that are within three hundred feet of any school, church or daycare center.

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

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

E. Revocation of registry identification card, licensed primary caregiver card, license to produce or distribute: Violation of any provision of this rule may result in the immediate revocation of any privilege granted under this rule and the act.
[7.34.4.14 NMAC - Rp, 7.34.4.12 NMAC, 12/30/2010]

7.34.4.15 MONITORING AND CORRECTIVE ACTIONS:

A. Monitoring:

(1) The department or its designee may perform on-site assessments of a licensed producer to determine compliance with these rules. The department may enter a facility at any time to assess or monitor.

(2) Twenty-four (24) hours' notice shall be provided to licensed producers who are qualified patients prior to an on-site assessment, except when the department has reasonable suspicion to believe that providing notice will result in the destruction of evidence or that providing such notice will impede the department's ability to enforce these regulations.

(3) The department may review any and all employee, qualified patient or primary caregiver records or conduct interviews with employees, qualified patients, primary caregivers or private licensed producers for the purpose of determining compliance with these requirements.

(4) All licensed producers shall provide the department or the department's designee immediate access to any material and information necessary for determining compliance with these requirements.

(5) Failure by the licensed producer to provide the department access to the premises or information may result in the revocation of the licensed producer's license and referral to state law enforcement.

(6) Any failure to adhere to these rules documented by the department during monitoring may result in sanction(s), including suspension, revocation, non-renewal or denial of licensure and referral to state or local law enforcement.

(7) The department shall refer non-frivolous complaints involving alleged criminal activity made against a licensed producer to the appropriate New Mexico state or local authorities.

B. Financial records: A licensed non-profit private entity shall maintain detailed confidential sales records in a manner and format approved by the department, and shall inform the department of the location where such records are kept, and promptly update that information if the records are removed.

(1) Access: The department or its agents shall have reasonable access to the sales and other financial records of a private entity licensee, and shall be granted immediate access to those records upon request. A patient shall be granted reasonable access to sales records of that patient upon request.

(2) Audit: A non-profit private entity shall submit the results of an annual financial audit to the department no later than January 31st of each year. The annual audit shall be conducted by an independent certified public accountant; the costs of any such audit shall be borne by the private entity. Results of the annual audit shall be forwarded to the medical cannabis program manager or designee. The department may also periodically require, within its discretion, the audit of a non-profit private entity's financial records by the department.

(3) Quarterly reports: A non-profit producer shall submit reports on at least a quarterly basis, or as otherwise requested, and in the format specified by the department.

C. Corrective action:

(1) If violations of requirements of this rule are cited as a result of monitoring or review of financial records, the licensed producer shall be provided with an official written report of the findings within seven (7) business days following the monitoring visit or the review of financial records.

(2) Unless otherwise specified by the department, the licensed producer shall correct the violation within five (5) calendar days of receipt of the official written report citing the violation(s).

(3) The violation shall not be deemed corrected until the department verifies in writing within seven (7) calendar days of receiving notice of the corrective action that the corrective action is satisfactory.

(4) If the violation has not been corrected, the department may issue a notice of contemplated action to suspend, revoke, or take other disciplinary action against the producer‘s license.

D. Suspension of license without prior hearing: In accordance with the Public Health Act, Section 24-1-5 (H) NMSA 1978, if immediate action is required to protect the health and safety of the general public, the qualified patient or primary caregivers, the program manager or designee may suspend the qualified patient, primary caregiver or licensed producer's license without notice.

(1) A licensee whose license has been summarily suspended is entitled to a record review not later than thirty (30) calendar days after the license was summarily suspended.

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

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

(4) The sole issue at a record review on a summary suspension is whether the licensee's license shall remain suspended pending a final adjudicatory hearing and subsequent ruling by the secretary.

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

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

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

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

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

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

[7.34.4.15 NMAC - Rp, 7.34.4.13 NMAC, 12/30/2010]

7.34.4.16 DISCIPLINARY ACTIONS AND APPEAL PROCESS:

A. Revocation of producer license: Violation of any provision of this rule may result in either the summary suspension of a producer's license by the medical cannabis program manager or designee, or issuance of a notice of contemplated action by the program manager or designee to suspend, revoke or take other disciplinary action against the producer's license and revoke (or otherwise affect) lawful privileges under the Lynn and Erin Compassionate Use Act, NMSA 1978, Section 26-2B-1 *et seq*.

B. Grounds for disciplinary action. A license may be revoked or suspended, or have other disciplinary action taken against it, and a renewal application may be denied, for:

(1) failure to comply with or satisfy any provision of this rule;

(2) failure to allow a monitoring visit by authorized representatives of the department;

(3) falsification of any material or information submitted to the department;

(4) diversion of cannabis, as determined by the department; and

(5) threatening or harming a patient, a medical practitioner, or an employee of the department.

C. Request for hearing: A producer whose license has been summarily suspended or who has received a notice of contemplated action to suspend, revoke or take other disciplinary action may request a hearing, in addition to a request for an administrative review of written materials (as applicable), for the purpose of review of such action. The appellant shall file the request for hearing within thirty (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; a statement of the facts relevant to the review of the action;

(2) state the requestor's name, address and telephone numbers;

(3) include a statement of the provision of the act and the rules promulgated under the act that are relevant to the review of the action;

(4) include a statement of the arguments that the appellant considers relevant to the review of the action; and

(5) include any other relevant evidence.

D. 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, NM or, with the consent of the parties, in another location.

(3) Due to federal and state confidentiality laws, hearings held pursuant to this section 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.

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

(4) notice to any other parties to give prompt notice of issues controverted in fact or law; and

(5) all necessary telephone numbers if a telephonic hearing shall be conducted.

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

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

(1) all pleadings, motions and intermediate rulings;

(2) evidence and briefs received or considered;

(3) a statement of matters officially noticed;

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

(5) proposed findings and conclusions; and

(6) any action recommended by the hearing examiner.

H. A party may request a transcription of the proceedings: The party requesting the transcript shall endure the cost of transcription.

I. Procedures and evidence:

(1) A party may be represented by a person licensed to practice law in New Mexico, a non-lawyer representative, or an individual appellant may represent him 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) Documentary and other physical evidence shall be authenticated or identified by any reasonable means that shows that the matter in question is what the proponent claims it to be.

(4) 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.

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

(1) the appellant shall present an opening statement on the merits and the appellee shall make a statement of the defense or reserve the statement until presentation of that party's case;

(2) after the opening statements, if made, the appellant shall present its case in chief in support of the appellant's petition;

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

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

(5) after presentation of the evidence by the parties, the appellant shall present a closing argument; the appellee then shall present his or her closing argument and the appellant shall present a rebuttal argument; and

(6) thereafter, the matter shall be submitted for recommendation by the hearing examiner.

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

L. Continuances: The hearing examiner shall not grant a continuance except for good cause shown. A motion to continue a hearing shall be made at least ten (10) calendar days before the hearing date.

M. Telephonic hearings:

(1) Any party requesting a telephonic hearing shall do so within ten (10) business days of the date of the notice. Notice of the telephonic hearing shall be made to all parties and shall include all necessary telephone numbers.

(2) The appellee shall initiate the telephone call. The appellant is responsible for ensuring the telephone number to the appellant's location for the telephonic hearing is accurate and the appellant is available at said telephone number at the time the hearing is to commence. Failure to provide the correct telephone number or failure to be available at the commencement of the hearing shall be treated as a failure to appear and shall subject the petitioner to a default judgment.

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

N. Recommended action and final decision:

(1) At the request of the hearing examiner or upon motion by either party granted by the hearing examiner and before the hearing examiner recommends action by the secretary, the parties shall submit briefs including findings of fact and conclusions of law for consideration by the hearing examiner. The hearing examiner holds the discretion to request briefs or grant a motion to submit briefs on any point of law deemed appropriate by

the hearing examiner. Briefs submitted shall include supporting reasons for any findings or legal conclusions and citations to the record and to relevant law.

(2) No more than thirty (30) calendar days after after the last submission by a party, the hearing examiner shall prepare a written decision containing his or her recommendation of action to taken by the secretary. The recommendation shall propose to sustain, modify or reverse the initial decision of the department.

(3) The secretary shall accept, reject or modify the hearing examiner's recommendation no later than ten (10) calendar days after receipt of the hearing examiner's recommendation. The final decision or order shall be issued in writing and shall include a statement of findings and conclusions and the reasons thereof, on all material issues of fact, law or discretion involved, together with a statement of the specific action taken to sustain, modify or reverse the initial decision of the hearing examiner. Service shall be made by mail.

(4) The final decision or order shall be made a part of the non-profit private entity's file with the medical cannabis program.

[7.34.4.16 NMAC - Rp, 7.34.4.14 NMAC, 12/30/2010]

7.34.4.17 EXEMPTION FROM STATE CRIMINAL AND CIVIL PENALTIES FOR THE MEDICAL USE OF CANNABIS:

A. No licensed producer or employee of the licensed producer, qualified patient licensed as a producer or licensed primary caregiver shall be subject to arrest, prosecution or penalty, in a manner for the production, possession, distribution or dispensation of cannabis in accordance with this rule and the act.

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

[7.34.4.17 NMAC - Rp, 7.34.4.15 NMAC, 12/30/2010]

7.34.4.18 LICENSED PRODUCER CONFIDENTIALITY: The department shall maintain a confidential file containing the names, addresses and telephone numbers of the persons or entities who have either applied for or received a license for the purpose of producing cannabis for medical use. Any financial records of any such person or entity that are held by the department shall remain confidential and not subject to public disclosure, with the exception of reports created by the department, or reports collected by the department from non-profit producers. Individual names of producers and patients shall be confidential and not subject to disclosure, except:

A. 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;

B. 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; or

C. as provided in the federal Health Insurance Portability and Accountability Act of 1996.

[7.34.4.18 NMAC - Rp, 7.34.4.16 NMAC, 12/30/2010]

7.34.4.19 DISPOSAL OF UNUSED CANNABIS BY QUALIFIED PATIENTS: Unused cannabis in the possession of a patient who holds a personal production license may be disposed of by transporting the unused portion to a state or local law enforcement office, or by destroying the unused cannabis.

[7.34.4.19 NMAC - Rp, 7.34.4.17 NMAC, 12/30/2010]

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

[7.34.4.20 NMAC - Rp, 7.34.4.18 NMAC, 12/30/2010]

7.34.4.21 SEVERABILITY: If any part or application of these rules is held to be invalid, the remainder or its application to other situations or persons shall not be affected. Any section of these rules legally severed shall not interfere with the remaining protections provided by these rules and the act.
[7.34.4.21 NMAC - Rp, 7.34.4.19 NMAC, 12/30/2010]

HISTORY OF 7.34.4 NMAC:

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

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