

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

7.34.4.1 ISSUING AGENCY: New Mexico Department of Health, Medical Cannabis Program.
[7.34.4.1 NMAC - Rp, 7.34.4.1 NMAC, 2/27/2015; [Rp, xx/xx/xxxx](#)]

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

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

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

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

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

7.34.4.7 DEFINITIONS:

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

B. “Adequate supply” means an amount of cannabis, ~~derived solely from an intrastate source and in any form approved by the department, that is~~ possessed by a qualified patient or collectively possessed by a qualified patient and the qualified ~~patient’s~~ patient’s primary caregiver; that is determined by rule of 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 and that is derived solely from an intrastate source;~~.

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

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

E. “Advisory board” means the medical cannabis advisory board consisting of nine practitioners knowledgeable about the medical use of cannabis, who are appointed by the secretary.

F. “Applicant” means any person applying for enrollment or re-enrollment in the medical cannabis program as a qualified patient, primary caregiver, or licensed producer.

~~_____ G. “Approved laboratory” means a licensed cannabis testing facility as defined in the Lynn and Erin Compassionate Use Act, Subsection I of Section 26-2B-3 NMSA 1978 that has been approved by the department specifically for the testing of cannabis, concentrates, and cannabis derived products.~~

~~_____ G. “Approved entity” means a manufacturer, laboratory, or courier.~~

~~_____ H. “Batch” means, with regard to usable cannabis, a homogenous, an identified quantity of cannabis no greater than five pounds that is of the same strain of cannabis, that is harvested during at the same specified time period from at the same specified cultivation area, and with respect to which the same agricultural practices were utilized, including the use of any pesticides; 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. _____ I. “Cannabis” means all parts of the plant Cannabis sativa L. containing a delta-9-tetrahydrocannabinol concentration of more than three-tenths percent on a dry weight basis, whether growing or not; the seeds of the plant; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture or preparation of the plant, its seeds or its resin; and does not include the mature stalks of the plant; fiber produced from the stalks; oil or cake made from the seeds of the plant; any other compound, manufacture, salt, derivative, mixture or preparation of the mature stalks, fiber, oil or cake; the sterilized seed of the plant that is incapable of germination; the weight of any other ingredient combined with cannabis to prepare topical or oral administrations, food, drink or another product; or hemp.~~

~~_____ J. “Cannabis consumption area” means an area within a licensed nonprofit producer’s premises that is approved by the department, where cannabis may be consumed by qualified patients, in accordance with department rules;~~

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

~~_____ L. “Cannabis establishment” means: (1) a licensed cannabis courier; (2) a licensed cannabis testing facility; (3) a licensed cannabis manufacturer; (4) a licensed non-profit producer; or (5) such other person that the department may by rule approve for participation in the medical cannabis program;~~

~~_____ M. “CBD means cannabidiol, a cannabinoid and the primary non-psychoactive ingredient found in cannabis.~~

~~_____ N. “CBDA” means cannabidiolic acid, a non-psychoactive ingredient found in cannabis and an acid precursor to CBD.~~

~~_____ O. “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.~~

~~_____ P. “Courier” means a person or entity cannabis courier as defined by the Lynn and Erin Compassionate Use Act, Subsection D of Section 26-2B-3 NMSA 1978, that transports has been approved by the department specifically to transport usable cannabis and cannabis products within the state of New Mexico, from a licensed non-profit producer cannabis establishment to a qualified patient or, a primary caregiver, to or another non-profit producer, to an approved laboratory, or to an approved manufacturer cannabis establishment.~~

~~_____ Q. “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;~~
- ~~(8) amyotrophic lateral sclerosis;~~
- ~~(9) Crohn’s disease;~~
- ~~(10) hepatitis C infection;~~
- ~~(11) Huntington’s disease;~~

- (12) inclusion body myositis;
- (13) inflammatory autoimmune-mediated arthritis;
- (14) intractable nausea or vomiting;
- (15) obstructive sleep apnea;
- (16) painful peripheral neuropathy;
- (17) Parkinson's disease;
- (18) posttraumatic stress disorder;
- (19) severe chronic pain;
- (20) severe anorexia or cachexia;
- (21) spasmodic torticollis;
- (22) ulcerative colitis; or
- (23) any other medical condition, medical treatment, or disease as approved by the department

which results in pain, suffering, or debility for which there is credible evidence that medical use cannabis could be of benefit.

OR. “Department” means the department of health or its agent.

~~_____P.~~ **S.** “Diversion” means the unlawful transfer of a cannabis plant, plant material, or cannabis-derived product.

T. “Dried usable cannabis” means the dried leaves, flowers, and trim of the female cannabis plant, but does not include the seeds, stalks, or roots of the cannabis plant.

U. “Facility” means any building, space, or grounds licensed for the production, possession, testing, manufacturing, or distribution of cannabis, concentrates, or cannabis-derived products.

QV. “Hemp” means the plant *cannabis sativa L.* and any part of the plant, whether growing or not, containing a delta-9-tetrahydrocannabinol concentration of no more than three-tenths percent on a dry weight basis;

W. “Intrastate” means existing or occurring within the state boundaries of New Mexico.

~~_____R.~~ **X.** “Inversion” means the unlawful acquisition of a cannabis plant, plant material, or cannabis-derived product.

Y. “Laboratory” means a licensed cannabis testing facility as defined in the Lynn and Erin Compassionate Use Act, Subsection I of Section 26-2B-3 NMSA 1978, that has been approved by the department specifically for the testing of cannabis, concentrates, and cannabis derived products.

Z. “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.

~~_____TAA.~~ “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.~~ **BB.** “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.

WCC. “Male plant” means a male cannabis plant.

~~_____XDD.~~ “Manufacture” means to ~~make or otherwise produce-prepare a~~ cannabis-derived product ~~or concentrate.~~

YEE. “Manufacturer” means a ~~person~~cannabis manufacturer as defined in the Lynn and Erin Compassionate Use Act, Subsection F of Section 26-2B-3 NMSA 1978, that ~~is licensed~~has been approved by the department specifically to manufacture cannabis products; package, transport or courier cannabis products; have cannabis products tested by a cannabis testing facility; purchase, obtain, sell and transport cannabis products to other cannabis establishments; and prepare products for personal production license holders.

ZFF. “Mature female plant” means a harvestable female cannabis plant that is flowering.

AAGG. “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.

BBHH. “Medical cannabis program ~~manager~~director” means the administrator of the medical cannabis program who holds that title.

CCII. “**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.

DDJJ. “**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.

EEKK. “**Minor**” means an individual who is less than 18 years of age.

FFLL. “**Non-profit producer**” means a New Mexico corporation that has been designated as a non-profit corporation by the New Mexico Secretary of State, that has been licensed by the department to possess, produce, dispense, distribute and manufacture cannabis and cannabis products and sell wholesale or by direct sale to qualified patients and primary caregivers.

GGMM. “**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.

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

HOO. “**Permanent structure**” means a building or structure that is placed on the land for the foreseeable future that is anchored to a permanent foundation, that is roofed and walled, and which requires a building permit from a local and or state governing authority.

PP. “**Personal production license**” means a license issued to a qualified patient or to a qualified patient’s primary caregiver participating in the medical cannabis program to permit the qualified patient or the qualified patient's primary caregiver to produce cannabis for the qualified patient's use at an address approved by the department.

JJ QO. “**Pesticide**” means a pesticide as defined by the New Mexico Pesticide Control Act, section 76-4-3, NMSA 1978;

RR. “**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.

KKSS. “**Plant**” means any cannabis plant, cutting, or clone that has roots or that is cultivated with the intention of growing roots.

LLTT. “**Policy**” means a written statement of principles that guides and determines present and future decisions and actions of the licensed producer.

MMUU. “**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.

NNVV. “**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.

OOVV. “**Primary caregiver application form**” means the registry identification card application form provided by the medical cannabis program.

PPXX. “**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.

QQ YY. “**Produce**” means to engage in any activity related to the planting or cultivation of cannabis;

ZZ. “**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.

RAAA. “**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.

SS BBB. “**Recall**” means to request the return of a product after the discovery of a safety issue or product defect;

CCC. “**Reciprocal limit**” means the quantity of cannabis and cannabis products that a reciprocal participant can use and possess in a given year pursuant to department rule;

DDD. **“Reciprocal participant”** means an individual who holds proof of authorization to participate in the medical cannabis program of another state of the United States, the District of Columbia, a territory or commonwealth of the United States or a New Mexico Indian nation, tribe or pueblo;

EEE. **“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.

TFFFF. **“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.

UUGGG. **“Secretary”** means the secretary of the New Mexico department of health.

VVHHH. **“Secure grounds”** means a facility that provides a safe environment to avoid loss or theft.

WWIII. **“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.

XXJJJ. **“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.

YYKKK. **“Seedling”** means a cannabis plant that has no flowers and that is less than 12 inches in height, as measured vertically in the plant’s natural position from the uppermost part of the root system (or from the soil line, if the plant is planted in soil) to the tallest point of the plant.

ZZLLL. **“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.

AAAMMM. **“THC”** means tetrahydrocannabinol, a cannabinoid that is the primary psychoactive ingredient in cannabis.

BBB NNN. **“THCA”** means tetrahydrocannabinolic acid, a non-psychoactive ingredient in cannabis and an acid precursor to THC.

OOO. **“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.

CCPPPP. **“Telemedicine”** means the use of telecommunications and information technology to provide clinical health care from a site apart from the site where the patient is located, in real time or asynchronously, including the use of interactive simultaneous audio and video or store-and-forward technology, or off-site patient monitoring and telecommunications in order to deliver health care services.

DDDDQQQ. **“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.

EEERRR. **“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.

FFFSSS. **“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.

TTT. **“Wastage”** means the destruction of usable cannabis or cannabis plants.

[7.34.4.7 NMAC - Rp, 7.34.4.7 NMAC, 2/27/2015; A, 2/29/2016; A, 8/27/2019; Rp, xx/xx/xxxx]

7.34.4.8 PRODUCER LICENSING; GENERAL PROVISIONS:

A. The department may license two classes of producers:

(1) A qualified patient or primary caregiver who holds a valid personal production license. A qualified patient or primary caregiver who holds a valid personal production license is authorized to possess no more than four mature female plants and a combined total of 12 seedlings and male plants, and may possess no more than an adequate supply of usable cannabis, as specified in department rule; provided that a qualified patient or qualified patient’s primary caregiver may possess that qualified patient’s harvest of cannabis. A personal production license holder may additionally obtain usable cannabis, seeds, or plants from licensed non-profit producers. The primary caregiver of a qualified patient who holds a personal production license may assist the qualified patient to produce medical cannabis at the designated licensed location that is identified on the personal production license.

(2) A non-profit producer that operates a facility and, at any one time, is limited to a combined total of no greater than 1,750 cannabis plants, not including seedlings, and an inventory of usable cannabis and seeds that reflects current patient needs. A non-profit producer may possess any quantity of seedlings, as defined in this rule. A non-profit producer shall not possess a quantity of cannabis plants that exceeds the quantities authorized by their licensure and associated licensing fee. A licensed non-profit producer may sell and distribute usable cannabis to a person or entity authorized to possess and receive it. A licensed non-profit producer may obtain plants, seeds and usable cannabis from other licensed non-profit producers.

B. Increase to non-profit producer plant limit: The department may increase the cannabis plant limitation for a licensed non-profit producer in accordance with the following:

(1) Effective June 1, 2021, a non-profit producer may request an increase of up to 500 plants that exceeds the total plants allowed in Paragraph (2) of Subsection A of 7.34.4.8 NMAC at the time of renewal of its licensure period. In order to be considered for approval by the department, the non-profit producer shall demonstrate a need for the plant count increase to meet demand for their qualified patients. The non-profit producer shall provide the following information to the department to demonstrate the need for a plant count increase:

(a) Average yield of usable cannabis flower and trim produced by the non-profit producer from the past 12 months;

(b) Current reported inventory of cannabis and cannabis-derived products;

(c) Percentage of usable cannabis and cannabis-derived products that was sold to qualified patients, primary caregivers, or to another licensed producer or manufacturer; and

(d) Any other information requested by the department.

(2) The department shall make a determination to approve or deny the non-profit producer's request to increase plant count based on the following factors:

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

(b) The non-profit producer's current inventory and average yield of usable cannabis is consistent with current averages from other licensed producers;

(c) The number and severity of complaints and enforcement actions on the non-profit licensed producer;

(d) The information provided by non-profit producer is consistent with the quarterly reports or inventory tracking information it has provided to the department within the last 12 months;

(e) Supply and demand of medical cannabis throughout the state and in underserved geographical regions; and

(f) The completeness of information and data provided to the department.

(3) Effective June 1, 2021, a non-profit producer may request an emergency increase once per year outside of their license renewal period, of up to 500 plants that exceeds the total plants allowed in section Paragraph (2) of Subsection A of 7.34.4.8 NMAC, at any time. The non-profit producer shall demonstrate a need for the plant count increase to meet demand for their qualified patients, and shall submit to the department the information identified in Paragraph (1) of Subsection B of 7.34.4.8 NMAC. The department shall only approve the request if the non-profit producer can demonstrate by clear and convincing evidence that it is not able to meet qualified patient demand for usable cannabis or cannabis-derived products with its current plant count or by obtaining usable cannabis or cannabis products from another licensed producer. The non-profit producer shall provide objective data about the current supply in the medical cannabis market to demonstrate these factors. The department shall also consider the same factors in Subsection B when approving or denying this request.

(4) Any increase in plant count approved under this section shall be voided in the event of a transfer of the majority of ownership for a licensed producer, at which time the plant limit for the license shall revert to the limit allowed in Paragraph (2) of Subsection A above.

(5) The department is not required to approve a request for an increase to a non-profit producer's plant limit and retains sole discretion to grant or deny the request.

C. Limitation on distribution: A non-profit producer shall not knowingly sell or otherwise distribute usable cannabis to any person or entity that is not authorized to possess and receive the usable cannabis pursuant to department rules.

D. Processing of production applications:

(1) The issuance of an application is in no way a guarantee that the completed application will be accepted or that a license will be granted. Information provided by the applicant and used by the licensing authority for the licensing process shall be accurate and truthful. Any applicant that fails to participate in good faith or that falsifies information presented in the licensing process shall have its application denied by the department.

(2) The number of licenses issued by the department to non-profit private entities, and the determination of which non-profit entities shall be licensed, shall be determined at the discretion of the secretary, which determination shall constitute the final administrative decision of the department.

(3) ~~A non-profit producer~~An applicant whose application for licensure is not approved shall not be entitled to further administrative review.

E. Factors considered: The secretary shall consider the overall health needs of qualified patients and the safety of the public in determining the number of licenses to be issued to non-profit private entities and shall further consider:

- (1) the sufficiency of the overall supply available to qualified patients statewide;
- (2) the service location of the applicant;
- (3) the applicant's production plan, including but not limited to the applicant's plan for the growth, cultivation, and harvesting of medical cannabis;
- (4) the applicant's sales and distribution plan, including but not limited to the applicant's plan for sale of medical cannabis, plan for delivery (if any) to qualified patients, and the forms of usable cannabis and cannabis-derived products to be sold or distributed;
- (5) the applicant's skill and knowledge of horticulture and cannabis production technology, as well as the applicant's knowledge of current good manufacturing practice in manufacturing, packaging, labeling, or holding operations for dietary supplements; environmental protection agency agricultural worker protection standards; and New Mexico department of agriculture (NMDA) pesticide registration, licensing and use requirements to ensure a safe product and environment;
- (6) the applicant's plan for the manufacture or distribution of cannabis derived products, including but not limited to edible products;
- (7) the security plan proposed, including location, security devices employed, and staffing;
- (8) the applicant's quality assurance plan, including but not limited to the applicant's plan to ensure purity, consistency of dose, as well as the applicant's plan for routine testing by a department approved laboratory;
- (9) the experience and expertise of the non-profit board members;
- (10) the financial resources available to the applicant for licensure and operations;
- (11) the facilities available to the applicant for production, distribution, storage, and other purposes, and the applicant's ownership of the property, buildings, or other facilities identified in the production and distribution plan, as applicable; and
- (12) other relevant factors.

F. Production and distribution of medical cannabis by a licensed non-profit producer; use of couriers: Production and distribution of medical cannabis by a licensed non-profit producer to a qualified patient or primary caregiver shall take place at locations described in the non-profit producer's production and distribution plan approved by the department, and shall not take place at locations that are within 300 feet of any school, church, or daycare center. ~~For purposes of that existed within the 300-foot area before the producer became licensed to operate at the location; provided that this provision, delivery distance requirement shall not apply to distribution at the residence/home of a~~ qualified patient or primary caregiver ~~shall not be deemed "distribution"~~. A licensed non-profit producer may, consistent with this rule, and with the consent of a purchasing qualified patient or primary caregiver, utilize an approved courier to transport usable cannabis to a qualified patient or primary caregiver, and may for this purpose share with an approved courier the contact information of the purchasing qualified patient or primary caregiver. A licensed non-profit producer may, consistent with this rule, also utilize an approved courier to transport usable cannabis to another non-profit producer, to an approved laboratory, and to an approved manufacturer. A licensed non-profit producer shall not identify any person as an intended recipient of usable cannabis who is not a qualified patient, a primary caregiver, an approved courier, an approved manufacturer, or an approved laboratory.

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

- (1) contacting the applicant by telephone, mail, or electronic mail;
- (2) conducting an on-site visit;
- (3) requiring a face-to-face meeting and the production of additional identification materials if proof of identity is uncertain; and
- (4) requiring additional relevant information as the department deems necessary.

H. Cooperation with the department: Upon submitting an application, an applicant shall fully cooperate with the department and shall timely respond to requests for information or documentation. Failure to

cooperate with a request of the department may result in the application being denied or otherwise declared incomplete.

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

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

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

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

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

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

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

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

L. Limitation on sales within 90 consecutive calendar days: A licensed non-profit producer shall not sell or distribute usable cannabis to a qualified patient or primary caregiver in a total quantity that exceeds 230 units, as described in department rules concerning patient registry identification cards, within any 90-day period, unless the qualified patient or primary caregiver presents proof of a valid medical exception granted by the department.

M. Destruction of usable cannabis and cannabis plants: A licensed non-profit producer shall document the destruction of any usable cannabis or cannabis plants using a video recording, and shall retain the video recording of the destruction for no less than 120 days. A licensed non-profit producer shall make the video recording of the destruction available for the department's inspection or copying upon the department's request.

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

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

- (1) distribution criteria for qualified patients or primary caregivers appropriate for cannabis services, to include clear, legible photocopies of the registry identification card and New Mexico photo identification card of every qualified patient or primary caregiver served by the private entity;
- (2) testing criteria and procedures, which shall be consistent with the testing requirements of this rule;
- (3) alcohol and drug-free work place policies and procedures;
- (4) an attestation that no firearms will be permitted on any premises used for production or distribution by the non-profit entity;
- (5) employee policies and procedures to address the following requirements:
 - (a) job descriptions or employment contracts developed for every employee that identify duties, authority, responsibilities, qualifications, and supervision; and
 - (b) training materials concerning adherence to state and federal confidentiality laws.
- (6) personnel records for each employee that include an application for employment and a record of any disciplinary action taken;
- (7) on-site training curricula, or contracts with outside resources capable of meeting employee training needs, to include, at a minimum, the following topics:
 - (a) professional conduct, ethics, and patient confidentiality; and
 - (b) informational developments in the field of medical use of cannabis.
- (8) employee safety and security training materials provided to each employee at the time of his or her initial appointment, to include:
 - (a) training in the proper use of security measures and controls that have been adopted; and
 - (b) specific procedural instructions regarding how to respond to an emergency, including robbery or a violent accident.
- (9) a general written security policy, to address at a minimum:
 - (a) safety and security procedures;
 - (b) personal safety; and
 - (c) crime prevention techniques.
- (10) training documentation prepared for each employee and statements signed by employees indicating the topics discussed (to include names and titles of presenters) and the date, time, and place the employee received said training;
- (11) a written policy regarding the right of the private entity to refuse service;
- (12) a confidentiality policy to ensure that identifying information of qualified patients is not disclosed or disseminated without authorization from the patient, except as otherwise required by the department; and
- ~~(13)~~ (13) an attestation that the nonprofit producer will prohibit its employees and contractors from being under the influence of drugs or alcohol in the workplace; and
- (14) such other policies or procedures as the department may require.

P. Retention of training documentation: A non-profit producer shall maintain documentation of an employee's training for a period of at least six months after termination of an employee's employment. ~~Employee training documentation shall be made available within 24 hours of a department representative's request; the 24 hour period shall exclude holidays and weekends.~~

Q. Licensure periods:

(1) **Licensure period for non-profit producers:** The licensure period of a licensed non-profit producer shall be from August 1st (or the date of approval of the licensure application, if later) through July 31st of a given year. Exception; transition to revised 2019 rules: The licensure period for a licensed non-profit producer that would otherwise end on August 1, 2019 shall instead continue until September 30, 2019.

(2) **Licensure period for qualified patient producers:** A qualified patient's personal production license shall expire ~~annually~~ one year after the issuance of the personal production license, or at the end of ~~the person's~~ enrollment in the NM medical cannabis program, whichever occurs first.

~~(3) **Return of a license or identification card:**~~ (3) **Identification cards:** An employee of a licensed non-profit producer shall carry their department issued employee identification card at all times during their work, and shall present the card to law enforcement officials and to department officials upon request. An employee who is unable to produce their department issued identification card upon request shall not remain on the licensed premises, and shall produce the card for the department's inspection prior to returning to the licensed premises. 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.

R. Amended license:

(1) **Submittal of application for 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) ~~(a)~~ (a) change of location of a qualified patient who also holds a personal production license;

(2) ~~(b)~~ (b) 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 producer~~ name, capacity or any physical modification or addition to the facility; and

(3) ~~(c)~~ (c) substantial change to a ~~private entity's producer's~~ production plan or distribution plan, including any change to the type(s) of products produced or distributed, the ~~private entity's producer's~~ manufacturing plan (as applicable), the producer's method(s) of distribution, and security plan.

(2) **Process for incomplete application for amended license:** In the event that an application for amended licensure is determined by the program to be incomplete, the program will specify the information or materials that remain to be submitted. If the licensed producer does not submit the requested information or material, and does not otherwise contact the department regarding the application, within thirty days of receiving notice of the deficiency, the application will be closed as incomplete, and the licensed producer will be required to recommence the application in order to resume the application process.

S. Application for renewal of an annual production license:

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

(2) **Deadline for personal production license holders:** A patient who holds personal production licensure shall apply for renewal of their annual license no later than 30 days prior to the expiration of the license by submitting a renewal application to the department.

(3) **General submission requirements for qualified patients:** Qualified patients applying for personal production licensure shall submit:

(a) an application for issuance or renewal of a personal production license; and
(b) a non-refundable thirty dollar (\$30) application fee, except that the fee may be waived upon a showing that the income of the qualified patient is equal to or lesser than two hundred percent (200%) of the federal poverty guidelines established by the U.S. department of health and human services. 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.

T. Non-transferable registration of license:

(1) A license shall not be transferred by assignment or otherwise to other persons or locations. Unless the licensed producer applies for and receives an amended license, the license shall be void and returned to the department when any one of the following situations occurs:

- (a) ownership of the facility changes;
(b) location change;
(c) change in licensed producer;
(d) the discontinuance of operation; or
(e) the removal of all medical cannabis from the facility by lawful state authority.

(2) Transactions, which do not constitute a change of ownership, include the following:

(a) when applicable, changes in the membership of a corporate board of directors or board of trustees; and
(b) two or more corporations merge and the originally licensed corporation survives.

U. Automatic expiration of license:

~~(1)~~; **closure of nonprofit producer operations:** 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.

V. Display of license: The licensed producer shall maintain the license safely at the production location ~~and(s) and dispensary location(s) and shall~~ be able to produce the license immediately upon request by the department or law enforcement.

W. Fees applicable to applicants and licensees:

(1) **Non-profit producer application fee:** A non-profit producer shall submit with its initial application an application fee of ten thousand dollars (\$10,000). If the application is denied, the department shall issue a refund of nine thousand dollars (\$9,000) to the applicant.

(2) **Non-profit producer license fee:** A non-profit producer that is licensed shall submit to the medical cannabis program a non-refundable licensure fee before beginning operations, no earlier than July 1st of each renewal year and no later than August 1st of each renewal year, of: \$40,000 for the first 500 cannabis plants to be possessed by the non-profit producer; \$5,000 for each additional increment of 50 cannabis plants above 500 and up to a collective total of 1,000 cannabis plants; and \$6,000 for each additional increment of 50 cannabis plants above 1,000.

(3) **Exception; ~~Transition~~transition to revised LNPP fees, plant limits:** A fee that is paid by a non-profit producer in the year 2019 shall be tendered to the department no earlier than September 23, 2019 and no later than October 4, 2019.

~~(4)~~ (4) **Exception; newly licensed LNPPs:** The license fee to be paid by a non-profit producer that obtains initial licensure after the enactment of this revised rule shall be pro-rated based on the time remaining in the licensure period.

(5) **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

(6) **Replacement license fee:** A fifty dollar (\$50) payment is required for replacement of an identification card for an employee of a licensed non-profit producer, and for replacement of a personal production license card.

(7) **Payment:** Fees shall be paid by check, money order, or any other form of payment approved by the medical cannabis program ~~manager~~director or designee, and shall be made payable to the medical cannabis program of the department.

~~X~~ **X. Geographic requirements for initial licenses:** The department may require that a non-profit producer operate dispensaries in geographical locations of the state that are specified by the department as a precondition of initial licensure.

Y. 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.

Z. Reporting of theft to department: A non-profit producer shall submit to the department notification of any theft, robbery, break-in, or security breach that occurs on the producer's premises, no later than 10 calendar days after the producer first becomes aware of the event. The description shall include a description of any property that was stolen or destroyed, and the quantity of any usable cannabis that was stolen.

AA. Closure of applications period: The department may close the applications period during which applications for non-profit producer licenses will be accepted and reviewed.

7.34.4.9 NON-PROFIT PRODUCERS; MINIMUM STANDARDS FOR PRODUCTION OF CANNABIS: A non-profit producer shall comply with the following minimum requirements for the production of cannabis:

- A. General requirements:** A licensed non-profit producer shall ensure the following:
- (1) that all production activities are done on premises that are in compliance with state and local laws, including but not limited to zoning, occupancy, licensing, and building codes;
 - (2) that all equipment, implements, and fixtures that are used for the production of cannabis shall be used exclusively for the production of cannabis;
 - (3) that no cannabis plants other than those grown pursuant to the non-profit producer's production license from the department are grown on the licensed property of the non-profit producer, including but not limited to hemp plants;
 - (4) that production is conducted in a manner that does not allow cross-contamination from chemical or biological hazards;
 - (5) that production does not occur at a location that is within 300 feet of a school, church, or daycare center that existed within the 300-foot area before the producer became licensed to operate at the location;
 - (6) that any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including a boil, sore, or infected wound, or any other abnormal source of microbial contamination for whom there is a reasonable possibility of contact with preparation surfaces for cannabis, shall be excluded from any operations which may be anticipated to result in such contamination until the condition is corrected;
 - (7) that hand-washing facilities are provided that are adequate, accessible, and conveniently located, and that they are furnished with running water at a suitable temperature; hand-washing facilities shall be located in indoor production facilities, in restrooms, and wherever good sanitary practices require employees to wash or sanitize their hands, and shall be stocked with effective hand-cleaning and sanitizing preparations, and sanitary towel service or suitable drying devices;
 - (8) that all persons involved in preparing or handling medical cannabis conform to hygienic practices while on duty, including:
 - (a) maintaining adequate personal cleanliness;
- PRODUCER-**
- (b) washing hands thoroughly in an adequate hand-washing area before starting work, at any other time when the hands may have become soiled or contaminated, and both before putting gloves on and after removal of gloves;
 - (c) refraining from preparing or handling medical cannabis or cannabis derived products if the handler has or may have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, until such condition is corrected; and
 - (d) complying with the other requirements of this section;
 - (9) that there is sufficient space for placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations for production of medical cannabis;
 - (10) that litter and waste are properly removed, and the operating systems for waste disposal are maintained in an adequate manner so that they do not constitute a source of contamination in areas where cannabis is exposed;
 - (11) that all floors (other than earthen floors), walls, and ceilings that are located within a permanent structure are constructed in such a manner that they are washable, wipeable, and non-absorbent, and can be kept clean, and kept in good repair;
 - (12) that walls and ceilings remain free of water damage, and that fiberglass and other insulation material not be exposed;
 - (13) that there is adequate safety-type lighting in all areas where cannabis is processed or stored, and where equipment or utensils are cleaned;
 - (14) that the non-profit producer provides adequate screening or other protection against the entry of pests; rubbish shall be disposed of so as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage, or breeding place for pests;
 - (15) that building, fixtures, and other physical facilities where cannabis is produced are maintained in a sanitary condition;
 - (16) that all contact surfaces, including utensils and equipment used for preparation of cannabis, are cleaned and sanitized as frequently as necessary to protect against contamination;

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

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

(19) that toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of medical cannabis or cannabis derived products, and that otherwise satisfies the requirements of this rule;

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

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

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

(23) that the non-profit producer provide its employees with adequate, readily accessible, on-site toilet facilities that are maintained in a sanitary condition and good repair;

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

(25) that usable cannabis that can support the rapid growth of undesirable microorganisms are stored and transported in a manner that prevents the growth of these microorganisms;

(26) that storage and transportation of usable cannabis is accomplished under conditions that will maintain security and protect the usable cannabis against physical, chemical, and microbial contamination as well as against deterioration of the usable cannabis and the container;

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

(28) that all containers used for storage or transport of usable cannabis are washable, wipeable, and nonabsorbent;

(29) that all weighting or measuring devices that are used in the production or distribution of usable cannabis be appropriately documented as having undergone certified registration and calibration that is in accordance with applicable requirements of the New Mexico department of agriculture;

(30) that the non-profit producer will prohibit its employees and contractors from being under the influence of drugs or alcohol in the workplace; and

(31) that hemp, hemp extract, and hemp derived products, other than hemp paper, are not combined in any manner with usable cannabis intended to be sold or otherwise distributed by the non-profit producer.

[7.34.4.9 NMAC - N, xx/xx/xxxx]

7.34.4.10 TESTING OF USABLE CANNABIS: All dried usable cannabis produced by a non-profit producer that is not converted into a concentrated cannabis derived product, and all concentrated cannabis derived products produced, sold, manufactured by a non-profit producer or distributed by a non-profit producer manufacturer, shall be sampled for testing purposes by the licensed non-profit producer or manufacturer, and those samples shall be tested by an approved laboratory, consistent with the requirements of this rule and found to have passed all tests required by this rule, prior to the sale or distribution, or other use of the dried usable cannabis or concentrated cannabis derived product. Each batch of dried usable cannabis or cannabis concentrate, other than cannabis that will be converted into a concentrated cannabis derived product, shall be segregated and sampled, and by the non-profit producer that produced the batch, and the non-profit producer shall ensure that 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, and before the dried usable cannabis or any substance derived therefrom is incorporated into a cannabis derived product. Each batch of concentrated cannabis derived product shall be segregated and sampled by the manufacturer or non-profit producer that produced the batch, and the manufacturer or non-profit producer (as applicable) shall ensure that each sample is tested by an approved laboratory in accordance with the testing requirements of this rule, and determined by the manufacturer or non-profit producer (as applicable) to have passed the following individual testing requirements, before cannabis derived product from that batch is made available for sale or distribution.

A. Exception; staggered implementation: The department may within its discretion waive testing requirement(s) requirements of this section, in whole or in part, ~~if based on considerations such as the department determines that the number~~ ability of currently approved laboratories ~~approved to conduct a given test is insufficient for to process~~ 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, or in order to allow additional time for laboratories to implement revised testing standards.

B. Exception for previously tested cannabis: ~~A~~ Except as otherwise provided in this rule, a non-profit producer or manufacturer shall not be required to sample and test dried usable cannabis or a concentrated cannabis-derived product if the batch was previously sampled, and the sample was tested by another non-profit producer or manufacturer 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 a manufacturer or non-profit producer (as applicable) shall sample and test concentrated cannabis derived products, for microbiological contaminants, using an approved laboratory. ~~A dried cannabis prior to sale, distribution, or other use. A sample may be deemed to have passed the microbiological test if it satisfies the standards~~ the sample contains less than each action level 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> Table 1, Microbiological Testing Requirements, below.

Table 1. Microbiological Testing Requirements			
Final Product	Test Parameter	Action Level	Test Units
<u>Chopped or Powdered Botanicals (Dried Usable Cannabis Not Extracted)</u>	<u>Total Aerobic Microbial Count</u>	<u>>100000</u>	<u>cfu/g or cfu/mL</u>
	<u>Total Combined Yeast & Mold Count</u>	<u>>1000</u>	<u>cfu/g or cfu/mL</u>
	<u>Bile-tolerant Gram-negative Bacteria</u>	<u>>1000</u>	<u>cfu/g or cfu/mL</u>
	<u>Absence of Salmonella spp. & E. coli</u>	<u>Absent</u>	<u>In 10 grams cfu/g or cfu/mL</u>
	<u>Total Coliforms Count</u>	<u>>1000</u>	<u>cfu/g or cfu/mL</u>
<u>Powdered Botanical Extracts (Extracted or Processed Cannabis Product i.e. hash, bubble hash, rosin, kief)</u>	<u>Total Aerobic Microbial Count</u>	<u>>10000</u>	<u>cfu/g or cfu/mL</u>
	<u>Total Combined Yeast & Mold Count</u>	<u>>1000</u>	<u>cfu/g or cfu/mL</u>
	<u>Bile-tolerant Gram-negative Bacteria</u>	<u>>1000</u>	<u>cfu/g or cfu/mL</u>
	<u>Absence of Salmonella spp. & E. coli</u>	<u>Absent</u>	<u>In 10 grams cfu/g or cfu/mL</u>
	<u>Total Coliforms Count</u>	<u>>1000</u>	<u>cfu/g or cfu/mL</u>
<u>Tinctures (Solutions of Cannabis in Alcohol)</u>	<u>Total Aerobic Microbial Count</u>	<u>>10000</u>	<u>cfu/g or cfu/mL</u>
	<u>Total Combined Yeast & Mold Count</u>	<u>>1000</u>	<u>cfu/g or cfu/mL</u>
<u>Infusions (solutions of cannabis in water)</u>	<u>Total Aerobic Microbial Count</u>	<u>>100</u>	<u>cfu/g or cfu/mL</u>
	<u>Total Combined Yeast & Mold Count</u>	<u>>10</u>	<u>cfu/g or cfu/mL</u>
<u>Decoctions (Solutions of Cannabis derived)</u>	<u>Total Aerobic Microbial Count</u>	<u>>100</u>	<u>cfu/g or cfu/mL</u>

<u>by boiling in water for at least 15 minutes)</u>	<u>Total Combined Yeast & Mold Count</u>	<u>>10</u>	<u>cfu/g or cfu/mL</u>
<u>Fluid extracts (An alcoholic liquid extract made by percolation of Cannabis so that 1 mL of the fluid extract represents 1 g of the Cannabis)</u>	<u>Total Aerobic Microbial Count</u>	<u>>10000</u>	<u>cfu/g or cfu/mL</u>
	<u>Total Combined Yeast & Mold Count</u>	<u>>1000</u>	<u>cfu/g or cfu/mL</u>
<u>Nutritional Supplements with Botanicals</u>	<u>Total Aerobic Microbial Count</u>	<u>>100000</u>	<u>cfu/g or cfu/mL</u>
	<u>Total Combined Yeast & Mold Count</u>	<u>>1000</u>	<u>cfu/g or cfu/mL</u>
	<u>Absence of Salmonella spp. & E. coli</u>	<u>Absent</u>	<u>In 10 grams cfu/g or cfu/mL</u>
<u>Botanicals to be treated with boiling water before use (Dried Cannabis to which boiling water is added immediately prior to consumption)</u>	<u>Total Aerobic Microbial Count</u>	<u>>100000</u>	<u>cfu/g or cfu/mL</u>
	<u>Total Combined Yeast & Mold Count</u>	<u>>1000</u>	<u>cfu/g or cfu/mL</u>
	<u>Absence of E. coli</u>	<u>Absent</u>	<u>In 10 grams cfu/g or cfu/mL</u>
<u>Nutritional products with other highly refined ingredients (Edibles)</u>	<u>Total Aerobic Microbial Count</u>	<u>>1000</u>	<u>cfu/g or cfu/mL</u>
	<u>Total Combined Yeast & Mold Count</u>	<u>>100</u>	<u>cfu/g or cfu/mL</u>
	<u>Absence of E. coli</u>	<u>Absent</u>	<u>In 10 grams cfu/g or cfu/mL</u>
<u>Quantitative analysis results shall be rounded off to the first two significant digits.</u>			
<u>E. coli and Salmonella results shall be reported as Present or Absent.</u>			

(2) **Mycotoxin test:** A non-profit producer shall sample and test dried, usable cannabis ~~and~~, and a manufacturer or non-profit producer (as applicable) shall sample and test concentrated cannabis derived products, for mycotoxins, using an approved laboratory prior to sale, distribution, or other use. 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. The mycotoxin test shall be conducted in accordance with the testing requirements at Table 2, Mycotoxins Testing Requirements.

<u>Table 2. Mycotoxins Testing Requirements</u>					
<u>Targeted Mycotoxins</u>	<u>Chemical Name</u>	<u>Abbreviation</u>	<u>CAS Number</u>	<u>Method Reporting Level (µg/kg)*</u>	<u>Action Level (µg/kg)*</u>
<u>Aflatoxins</u>	<u>Aflatoxin B₁</u>	<u>AFB₁</u>	<u>1162-65-8</u>	<u>1.0</u>	<u>Combined concentration of five mycotoxin</u>
-	<u>Aflatoxin B₂</u>	<u>AFB₂</u>	<u>7220-81-7</u>	<u>1.0</u>	
-	<u>Aflatoxin G₁</u>	<u>AFG₁</u>	<u>1165-39-5</u>	<u>1.0</u>	

	<u>Aflatoxin G₂</u>	<u>AFG₂</u>	<u>7241-98-7</u>	<u>1.0</u>	<u>components:</u> <u>20</u>
<u>Ochratoxin</u>	<u>Ochratoxin A</u>	<u>OTA</u>	<u>303-47-9</u>	<u>1.0</u>	

Mycotoxins Reporting Requirements for DOH Medical Cannabis Program

Use two significant digits when reporting a total mycotoxins result.

Non-detects are reported as less than the Method Reporting Level. Example: "Total Mycotoxins < 1 µg/kg"

*Micrograms of mycotoxin per kilogram (µg/kg) of sample is equivalent to parts per billion (ppb).

(3) **Solvent residue****Residual solvent test:** A manufacturer or non-profit producer (as applicable) 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 prior to sale, distribution, or other use. A sample may be deemed to have passed the residual solvent test if the sample contains less than each action level set forth in Table 3, Residual Solvent Testing Requirements. The residual solvent test shall be conducted in accordance with the testing requirements at Table 3.~~

(4) **Quantity of THC and CBD**

<u>Table 3. Residual Solvent Testing Requirements</u>					
<u>Targeted Compounds</u>	<u>Common Chemical Name</u>	<u>IUPAC Name</u>	<u>CAS Number</u>	<u>Method Reporting Level (µg/g) or (ppm)*</u>	<u>Action Level (µg/g) or (ppm)*</u>
<u>Propane</u>	<u>propane</u>	<u>propane</u>	<u>74-98-6</u>	<u>100</u>	<u>500</u>
<u>Butanes</u>	<u>n-butane</u>	<u>butane</u>	<u>106-97-8</u>	<u>100</u>	<u>500</u>
	<u>isobutane</u>	<u>2-methylpropane</u>	<u>75-28-5</u>	<u>100</u>	<u>500</u>
<u>Pentane</u>	<u>n-pentane</u>	<u>pentane</u>	<u>109-66-0</u>	<u>100</u>	<u>500</u>
<u>Hexane</u>	<u>n-hexane</u>	<u>hexane</u>	<u>110-54-3</u>	<u>25</u>	<u>50</u>
<u>Cyclohexane</u>	<u>cyclohexane</u>	<u>cyclohexane</u>	<u>110-82-7</u>	<u>100</u>	<u>500</u>
<u>Benzene</u>	<u>benzene</u>	<u>benzene</u>	<u>71-43-2</u>	<u>2.0</u>	<u>2.0</u>
<u>Toluene</u>	<u>toluene</u>	<u>methylbenzene</u>	<u>108-88-3</u>	<u>100</u>	<u>200</u>
<u>Heptane</u>	<u>n-heptane</u>	<u>heptane</u>	<u>142-82-5</u>	<u>100</u>	<u>500</u>
<u>Ethylbenzene and Xylenes</u>	<u>ethylbenzene</u>	<u>ethylbenzene</u>	<u>100-41-4</u>	<u>100</u>	<u>Combined concentration of all four compounds:</u> <u>400</u>
	<u>ortho-xylene</u>	<u>1,2-dimethylbenzene</u>	<u>95-47-6</u>	<u>100</u>	
	<u>meta-xylene</u>	<u>1,3-dimethylbenzene</u>	<u>108-38-3</u>	<u>200</u>	
	<u>para-xylene</u>	<u>1,4-dimethylbenzene</u>	<u>106-42-3</u>		
<u>Methyl Alcohol</u>	<u>methyl alcohol</u>	<u>methanol</u>	<u>67-56-1</u>	<u>100</u>	<u>1000</u>
<u>Isopropyl Alcohol</u>	<u>isopropanol</u>	<u>2-propanol</u>	<u>67-63-0</u>	<u>200</u>	<u>1000</u>

<u>Methylene Chloride</u>	<u>methylene chloride</u>	<u>dichloromethane</u>	<u>75-09-2</u>	<u>50</u>	<u>100</u>
<u>Acetone</u>	<u>acetone</u>	<u>2-propanone</u>	<u>67-64-1</u>	<u>200</u>	<u>1000</u>
<u>Residual Solvents Reporting Requirements for DOH Medical Cannabis Program</u> Use two significant digits when reporting residual solvent results. Non-detects are reported as less than the Method Reporting Level for each residual solvent. Example: "Benzene < 2.0 µg/g" Note: The isomers meta-xylene and para-xylene cannot be separated chromatographically, so they are reported as a pair. *Micrograms solvent per gram of sample (µg/g) is equivalent to parts per million (ppm).					

(4) Potency test: A non-profit producer shall sample and test all dried usable cannabis ~~and~~, and a non-profit producer or manufacturer (as applicable) shall sample and test all concentrated cannabis derived products, for quantity of tetrahydrocannabinol (THC), tetrahydrocannabinolic acid (THCA), cannabidiol (CBD), cannabidiolic acid (CBDA), and also for THC potency and CBD potency, using an approved laboratory; prior to sale, distribution, or other use. A non-profit producer may, at the producer's option, also test for quantity of cannabinol (CBN), cannabigerolic acid (CBGA), cannabigerol (CBG), cannabichromene (CBC), tetrahydrocannabivarin (THCV), and cannabidivarin (CBDV). The potency test shall be conducted in accordance with the testing requirements at Table 4, Potency Testing Requirements.

(5)

<u>Table 4. Potency Testing Requirements</u>				
<u>Cannabinoid</u>	<u>Abbreviation</u>	<u>CAS Number</u>	<u>Reporting Units*</u>	<u>Comments</u>
<u>Tetrahydrocannabinolic Acid</u>	<u>THCA</u>	<u>23978-85-0</u>	<u>mg/g and % (Percent)</u>	<u>analysis required by rule</u>
<u>Tetrahydrocannabinol</u>	<u>THC</u>	<u>1972-08-3</u>	<u>mg/g and % (Percent)</u>	<u>analysis required by rule</u>
<u>Cannabidiolic Acid</u>	<u>CBDA</u>	<u>1244-58-2</u>	<u>mg/g and % (Percent)</u>	<u>analysis required by rule</u>
<u>Cannabidiol</u>	<u>CBD</u>	<u>13956-29-1</u>	<u>mg/g and % (Percent)</u>	<u>analysis required by rule</u>
<u>THC Potency</u>	<u>THC Potency = Percent THCA x 0.877 + Percent THC</u>		<u>mg/g and % (Percent)</u>	<u>reporting required by the rule and calculation listed</u>
<u>CBD Potency</u>	<u>CBD Potency = Percent CBDA x 0.877 + Percent CBD</u>		<u>mg/g and % (Percent)</u>	<u>reporting required by the rule and calculation listed</u>
<u>Cannabinol</u>	<u>CBN</u>	<u>521-35-7</u>	<u>mg/g and % (Percent)</u>	<u>analysis optional, recommended for strain characterization</u>
<u>Cannabigerolic Acid</u>	<u>CBGA</u>	<u>25555-57-1</u>	<u>mg/g and % (Percent)</u>	<u>analysis optional, recommended for strain characterization</u>
<u>Cannabigerol</u>	<u>CBG</u>	<u>25654-31-3</u>	<u>mg/g and % (Percent)</u>	<u>analysis optional, recommended for strain characterization</u>
<u>Cannabichromene</u>	<u>CBC</u>	<u>20675-51-8</u>	<u>mg/g and % (Percent)</u>	<u>analysis optional, recommended for strain characterization</u>

<u>Tetrahydrocannabivarin</u>	<u>THCV</u>	<u>31262-37-0</u>	<u>mg/g and % (Percent)</u>	<u>analysis optional, recommended for strain characterization</u>
<u>Cannabidivarin</u>	<u>CBDV</u>	<u>24274-48-4</u>	<u>mg/g and % (Percent)</u>	<u>analysis optional, recommended for strain characterization</u>
<u>*Milligrams per gram (mg/g) of sample; this unit can be also expressed in percent composition of the sample.</u>				

(a) Homogeneity in potency: A cannabis derived product shall be homogenous in composition with respect to THC potency. A product shall be deemed non-homogenous if 10% of the infused portion of the product contains more than 20% of the total THC contained in the product. In the event that a cannabis derived product does not meet this requirement, the batch shall be wasted in accordance with the provisions of this rule.

(5) Heavy metal test: A non-profit producer shall sample and test all dried usable cannabis, and a non-profit producer or manufacturer (as applicable) shall sample and test all concentrated cannabis derived products, for heavy metals, using an approved laboratory, prior to sale, distribution, or other use. A sample may be deemed to have passed the heavy metals test if the sample contains less than each action level set forth in Table 5, Heavy Metal Testing Requirements. The heavy metals test shall be conducted in accordance with the testing requirements at Table 5.

<u>Table 5. Heavy Metal Testing Requirements</u>					
<u>Heavy Metals</u>	<u>Elemental Symbol</u>	<u>IUPAC Name</u>	<u>CAS Number</u>	<u>Action Level (µg/g) or (ppm)*</u>	<u>Method Reporting Level (µg/g) or (ppm)*</u>
<u>Arsenic</u>	<u>As</u>	<u>arsenic</u>	<u>7440-38-2</u>	<u>2.0</u>	<u>0.2</u>
<u>Cadmium</u>	<u>Cd</u>	<u>cadmium</u>	<u>7440-43-9</u>	<u>0.8</u>	<u>0.2</u>
<u>Lead</u>	<u>Pb</u>	<u>lead</u>	<u>7439-92-1</u>	<u>1.2</u>	<u>0.2</u>
<u>Mercury</u>	<u>Hg</u>	<u>mercury</u>	<u>7439-97-6</u>	<u>0.4</u>	<u>0.1</u>
<u>*Micrograms per gram (µg/g) of sample is equivalent to parts per million (ppm).</u>					

(6) Pesticide test: A non-profit producer shall sample and test all dried usable cannabis, and a non-profit producer or manufacturer (as applicable) shall sample and test all concentrated cannabis derived products, for pesticide content using an approved laboratory prior to sale, distribution, or other use. A sample may be deemed to have passed the pesticide test if the sample contains less than each action level set forth in Table 6, Pesticide Testing Requirements. The pesticide test shall be conducted in accordance with the testing requirements at Table 6.

<u>Table 6. Pesticide Testing Requirements</u>				
<u>Targeted Pesticide</u>	<u>Common Chemical Name</u>	<u>CAS Number</u>	<u>Action Level (µg/kg)</u>	<u>Method Reporting Level (µg/kg)</u>
<u>Abamectin</u>	<u>avermectin B1a & avermectin B1b</u>	<u>71751-41-2</u>	<u>500</u>	<u>100</u>
<u>Azoxystrobin</u>	<u>azoxystrobin</u>	<u>131860-33-8</u>	<u>200</u>	<u>100</u>
<u>Bifenazate</u>	<u>bifenazate</u>	<u>149877-41-8</u>	<u>200</u>	<u>100</u>
<u>Etoxazole</u>	<u>etoxazole</u>	<u>153233-91-1</u>	<u>200</u>	<u>100</u>
<u>Imazalil</u>	<u>chloramizole</u>	<u>35554-44-0</u>	<u>200</u>	<u>100</u>
<u>Imidacloprid</u>	<u>imidacloprid</u>	<u>138261-41-3</u>	<u>400</u>	<u>100</u>

<u>Malathion</u>	<u>malathion</u>	<u>121-75-5</u>	<u>200</u>	<u>100</u>
<u>Myclobutanil</u>	<u>myclobutanil</u>	<u>88671-89-0</u>	<u>200</u>	<u>100</u>
<u>Permethrins</u>	<u>cis-permethrin & trans-permethrin</u>	<u>52645-53-1</u>	<u>200</u>	<u>100</u>
<u>Spinosad</u>	<u>spinosyn A & spinosyn D</u>	<u>168316-95-8</u>	<u>200</u>	<u>100</u>
<u>Spiromesifen</u>	<u>spiromesifen</u>	<u>283594-90-1</u>	<u>200</u>	<u>100</u>
<u>Spirotetramat</u>	<u>spirotetramat</u>	<u>203313-25-1</u>	<u>200</u>	<u>100</u>
<u>Tebuconazole</u>	<u>tebuconazole</u>	<u>80443-41-0</u>	<u>400</u>	<u>100</u>
*Micrograms of pesticide per kilogram (<u>µg/kg</u>) of sample is equivalent to parts per billion (ppb).				

(7) Moisture content test: A non-profit producer shall sample and test all dried usable cannabis for moisture content using an approved laboratory prior to sale, distribution, or other use.

(8) Random testing of finished cannabis derived products: A non-profit producer or manufacturer that manufactures a cannabis derived product shall establish a schedule for, and shall conduct, random sampling and testing of finished, non-concentrated cannabis derived products, including but not limited to edible cannabis derived products, as follows:

(a) The non-profit producer or manufacturer shall randomly select and sample at and at least one percent of all non-concentrated cannabis derived product batches manufactured every week (and no less than one batch);

(b) The non-profit producer or manufacturer shall apply the sampling and testing standards that otherwise apply under this rule to dried cannabis and concentrated cannabis derived products; and

(c) In the event that a sample fails any of the required tests, the batch shall not be sold, distributed, or otherwise used, unless remediated in accordance with the remediation standards of this rule.

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

D. Release of batch after testing: A licensed non-profit producer or manufacturer 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 and a manufacturer shall ensure that the following testing procedures are followed:

(1) sampling and segregation: a licensed non-profit producer or manufacturer shall remove a sample of no less than ~~three grams from every batch~~ the quantities of harvested, dried, usable cannabis, and no less than one gram from every batch of concentrated or cannabis-derived product, and specified in Table 7, Minimum Test Sample Size, from every batch, and shall 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)

<u>Table 7. Minimum Test Sample Size</u>			
<u>Targeted Parameter</u>	<u>Sample Matrix</u>	<u>Analysis Platforms (Instrumentation Used by Lab)</u>	<u>Minimum Amount Required for Testing (grams)</u>
<u>Cannabis Potency</u>	<u>dried usable cannabis</u>	<u>HPLC, LCMS</u>	<u>1.0</u>
	<u>concentrated cannabis-derived products (CCDP)</u>	<u>HPLC, LCMS</u>	<u>1.0</u>
	<u>non-concentrated cannabis-derived products (NCCDP)</u>	<u>HPLC, LCMS</u>	<u>1.0</u>
<u>Cannabis Moisture Content</u>	<u>dried usable cannabis</u>	<u>n/a</u>	<u>1.0</u>

<u>Mycotoxins</u>	<u>dried usable cannabis, CCDP, or NCCDP</u>	<u>HPLC, LCMS, LCMSMS</u>	<u>1.0</u>
<u>Residual Solvents</u>	<u>CCDP</u>	<u>GC-FID, GC-PID/FID</u>	<u>1.0</u>
	<u>CCDP</u>	<u>GCMS</u>	<u>0.5</u>
	<u>NCCDP</u>	<u>GC-FID, GC-PID/FID</u>	<u>5.0</u>
	<u>NCCDP</u>	<u>GCMS</u>	<u>1.0</u>
<u>Absence of Salmonella spp. & E. coli</u>	<u>dried usable cannabis, NCCDP</u>	<u>Culture, biochemical, antibody, or nucleic acid-based assays shall be validated microbiological methodology such as FDA, USP, AOAC, or equivalent.</u>	<u>10.0</u>
	<u>CCDP</u>		<u>1.0</u>
<u>Total Aerobic Microbial Count</u>	<u>dried usable cannabis, CCDP, or NCCDP</u>	<u>Direct culture, indirect culture, or non-culture based. Must be validated microbiological methodology such as FDA, USP, AOAC, or equivalent.</u>	<u>10.0 (dried usable cannabis and NCCDP) 1.00 (CCDP)</u>
<u>Total Combined Yeast & Mold Count</u>			
<u>Bile-tolerant Gram-negative Bacteria</u>			
<u>Total Coliforms Count</u>			
<u>Pesticides</u>	<u>dried usable cannabis</u>	<u>HPLC, LCMS, LCMSMS</u>	<u>2.0</u>
<u>Heavy Metals</u>	<u>dried usable cannabis, CCDP, NCCDP</u>	<u>ICP-MS, FIMS</u>	<u>0.5</u>

Minimum required test size for CCDP = 8 g. Minimum required test sample size for NCCDP = 27.5g.
Minimum required test sample size for dried usable cannabis = 25.5 g.
Minimum test sample size may change if a validated method is approved by NMDOH MCP

(2) **sample selection:** a non-profit producer and manufacturer shall collect and submit samples for testing that are representative of the batch being tested; the department may order that a non-profit producer or manufacturer modify its sampling collection practices if it has reason to believe that samples that were previously collected were not representative of an associated batch;

(3) **documentation:** a licensed non-profit producer and a manufacturer 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) (4) **preservation and inspection of testing records:** a licensed non-profit producer and a manufacturer shall maintain all results of laboratory tests conducted on cannabis or cannabis derived products produced by the licensed non-profit producer or ~~its~~ manufacturer or their 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

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

F. Remediation; subsequent testing: If a sample fails a given test (i.e., if the sample does not measure below the action levels specified in this rule), the non-profit producer or manufacturer (as applicable) shall determine whether remediation is appropriate, and may pursue confirmatory testing at another approved laboratory. In the event that a non-profit producer or manufacturer attempts to remediate cannabis or a cannabis derived product, the batch shall again be sampled and subjected to all of the tests identified in this rule, except those required for heavy metals and pesticides. A batch of usable cannabis that fails a given test, and that does not pass the required tests subsequent to remediation conducted in accordance with the terms of this rule, shall be destroyed in accordance with the wastage requirements of this rule. A non-profit producer or manufacturer may remediate cannabis or cannabis derived product in accordance with the following:

(1) Dried usable cannabis: A non-profit producer may remediate dried usable cannabis that has failed a microbiological test, by utilizing extraction or distillation methods that remove or reduce contaminants in the batch such that a subsequent sample from the batch measures within the action levels of a required test. A non-profit producer may not remediate dried usable cannabis that fails any other test required by this rule;

(2) Cannabis derived product: A non-profit producer or manufacturer (as applicable) may remediate a non-edible cannabis derived product (including concentrated product) that has failed a microbiological test or residual solvent test by utilizing extraction or distillation methods that remove or reduce contaminants in the batch such that a subsequent sample from the batch measures within the action levels of a required test. A non-profit producer or manufacturer may not remediate non-edible cannabis derived product that fails any other test required by this rule.

(3) Edible cannabis derived product: A non-profit producer or manufacturer may not remediate an edible cannabis derived product. Edible cannabis derived products include brownies, cookies, candies, and similar finished products intended for human consumption.

(4) Notice and wastage: If the batch of usable cannabis cannot be remediated such that the sample measures within the action levels of a required test, the non-profit producer or manufacturer shall notify the department within 24 hours, and shall confirm the wastage and disposal of the usable cannabis in accordance with this rule. The wasted product shall be removed from inventory, and the removal from inventory shall be tracked in an electronic system specified by the department.

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

[7.34.4.9] 10 NMAC - Rp, 7.34.4.8 NMAC, 2/27/2015; A, 2/29/2016; Rp. 7.34.4.9 NMAC, xx/xx/xxxx]

7.34.4.10 — 7.34.4.11 WASTAGE OF CANNABIS; PERMITTED METHODS: A non-profit producer or approved entity that wastes usable cannabis or cannabis plants shall do so by rendering the cannabis unusable and unrecognizable, in accordance with the requirements of this rule, prior to removal from licensed premises. The wastage of usable cannabis and cannabis plants shall be documented by the non-profit producer or approved entity, shall be tracked by batch, and shall be recorded in an electronic tracking system specified by the department. Wastage of usable cannabis or cannabis plants shall occur only within the licensee's ordinary business hours. A non-profit producer or approved entity shall dispose of wasted cannabis and shall not attempt to incorporate wasted cannabis products into any product intended for consumption.

A. Permitted methods of wastage: Wastage of cannabis and cannabis derived products shall be accomplished by the following permitted methods:

(1) Dried usable cannabis: Wastage of dried usable cannabis or cannabis plants shall be accomplished by grinding and incorporating the cannabis into other ground material, such as soil, compost material, or leaf and yard waste, so that the resulting mixture is at least fifty percent non-cannabis material by volume;

(2) Non-liquid cannabis derived product: Wastage of non-liquid cannabis derived products shall be accomplished in the same manner as the wastage of dried usable cannabis; and

(3) Liquid cannabis derived product: Wastage of cannabis derived liquids shall be accomplished by mixing the liquid with absorbent material such as cat litter, sand, plastic waste, or sawdust, such that the liquid is fully absorbed into the material.

B. Disposal of wasted cannabis: Disposal of wasted cannabis and cannabis products shall be conducted in accordance with all applicable waste disposal laws, including but not limited to hazardous waste disposal laws (as applicable).

C. Holding time: Usable cannabis and cannabis plants that a licensee intends to waste shall be held in a secured designated holding area for a minimum of 72 hours prior to being wasted. A licensee shall affix to each batch that is held for wasting documents that record information concerning the batch, including batch number or code, plant number, and weight. The batch to be wasted shall not be handled, moved, or wasted during the 72 hour period, unless by specific instruction of the department. Cannabis that is intended to be wasted may be subject to inspection by the department or its designee.

D. Documentation of wastage; retention: A licensee shall record the wastage of usable cannabis and cannabis plants, including batch number, weight, plant number, the name of the receiving solid waste facility, dates of wastage and disposal, and any test results associated with a wasted batch, using an electronic system specified by the department, and shall deduct any wasted usable cannabis or cannabis plants from the licensee's inventory. The electronic record shall be retained for no less than two years following the disposal. A licensee shall additionally document the wastage of any usable cannabis or cannabis plants using a video recording, and shall retain the video recording of the destruction for no less than 120 days. A licensee shall make the video recording of the destruction available for the department's inspection and copying upon the department's request.

E. Notice to department: A non-profit producer or manufacturer shall notify the department of the wastage of usable cannabis within five business days of the wastage.
[7.34.4.11 NMAC - N, xx/xx/xxxx]

7.34.4.12 DEPARTMENT TESTING; QUALITY ASSURANCE; RANDOMIZED TESTING; COMPLAINT PROCEDURE; DEPARTMENT TESTING:

A. Quality assurance testing by the department: The department may within its discretion conduct quality assurance sampling and testing of usable cannabis, and may require a producer or a manufacturer to provide samples of usable cannabis for this purpose. The department may additionally adopt and enforce a randomized testing schedule for the sampling and testing of usable cannabis. The department may prohibit the sale or distribution of usable cannabis that is determined by the department to contain prohibited levels of contaminants, or that is found to have been improperly tested, or may require remediation of such usable cannabis that is consistent with the remediation standards of this rule.

B. Complaints: If the department or its designee receives a complaint regarding the presence of mold, bacteria, or another contaminant in usable cannabis produced by a ~~licensed~~ non-profit producer, a manufacturer, 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 physical, microbiological, chemical, or ~~another~~ other contaminant may jeopardize the health of a patient, the department or its designee may conduct an unannounced visit to the producer or manufacturer and may require the producer or manufacturer to provide samples of medical cannabis for testing by the department. Producers and manufacturers shall bear the cost of any testing required by the department.

C. Department sampling and testing requirements: Medical cannabis program employees ~~or~~ and their designees may possess ~~those~~ medical cannabis samples for the sole purposes of testing or transport to a testing facility. The department or its designee shall comply with the following testing requirements:

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

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

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

D. (4) all testing samples shall be tested by the department or a designated testing facility; and

~~E. no more than eight grams~~ **(5)** the quantity of ~~medical~~ cannabis shall be that is gathered by the department from a producer or manufacturer for testing purposes ~~from a non-profit medical cannabis producer on any single occasion; and shall not exceed the applicable sample sizes identified in Table 7.~~

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

[7.34.4.10]2 NMAC - Rp, 7.34.4.8 NMAC, 2/27/2015; Rp. 7.34.4.10 NMAC, xx/xx/xxxx]

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

shall be stored in a secured area that is accessible only to employees, and shall be segregated from usable cannabis and cannabis plants and from any product or equipment that is utilized in the manufacturing or production process.
[7.34.4.~~11~~¹³ NMAC - N, 2/27/2015; Rp. 7.34.4.11 NMAC, xx/xx/xxxx]

7.34.4.~~12~~¹⁴ DEPARTMENT APPROVAL OF MANUFACTURERS OF CANNABIS DERIVED PRODUCTS; GENERAL MANUFACTURING PROVISIONS:

A. Submittal of applications: A manufacturer applicant shall submit an authorized application form to the program with each initial application and renewal application, together with a fee of ~~one~~^{five} thousand dollars (\$~~1~~⁵,000) issued to the medical cannabis program. A manufacturer applicant shall comply with the application requirements of this rule, and shall submit such other information as the manufacturer applicant wishes to provide or such information as the department may request for initial approval or periodic evaluation(s) during the approval period.

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

- (1) proof that the manufacturer applicant is in good standing with the New Mexico taxation and revenue department;
- (2) copies of the manufacturer applicant's articles of incorporation and by-laws, as applicable;
- (3) a complete written description of the means that the manufacturer applicant shall employ to safely manufacture cannabis-derived products, including but not limited to hygiene standards consistent with the requirements of this rule, and a hazard analysis critical control point plan (HACCP) for each type of product that the manufacturer wishes to manufacture;
- ~~(4)~~ (4) a detailed list of all cannabis derived products to be manufactured;
- (5) a list of all persons or business entities having direct or indirect authority over the management or policies of the manufacturer applicant;
- ~~(5)~~ a list of all persons or business entities having any ownership interest in any property utilized by the manufacturer applicant, whether direct or indirect, and whether the interest is in land, building(s), or other material, including owners of any business entity that owns all or part of land or building(s) utilized;
- ~~(6)~~ a description of the facilities that shall be used in the manufacture of cannabis derived products;
- ~~(7)~~ (8) proof that no buildings to be used by the manufacturer are located within 300 feet of any school, church, or daycare center; or alternatively, proof that any school, church, or daycare center that is located within 300 feet of a building to be used by the applicant did not occupy that location prior to the applicant initially seeking to become licensed to operate at the location;
- (9) a description of how the manufacturer applicant will obtain cannabis or cannabis concentrates from a licensed non-profit producer, and how the manufacturer applicant will transport cannabis derived products to a licensed non-profit producer, including but not limited to chain of custody documentation;
- ~~(8)~~ testing criteria and procedures, which shall be consistent with the testing requirements of this rule;
- (911) a general written security policy, to address at a minimum:
 - (a) safety and security procedures;
 - (b) personal safety; ~~and~~
 - (c) crime prevention techniques.
- ~~(10)~~ an attestation that no firearms will be permitted on any premises used for manufacture of cannabis derived products by the manufacturer applicant;
- ~~(11)~~ a description of the methods and device or series of devices that shall be used to provide security, as well as documentation of successful testing of alarms and law enforcement notification system;
- ~~(12)~~ training documentation prepared for each employee of the manufacturer applicant, statements signed by employees indicating the topics discussed (to include names and titles of presenters) and the date, time, and place the employee received said training;
- ~~(13)~~ employee policies and procedures to address the following requirements:
 - (a) job descriptions or employment contracts developed for every employee of the manufacturer applicant that identify duties, authority, responsibilities, qualifications, and supervision; and
 - (b) training materials concerning adherence to state and federal confidentiality laws.
- ~~(14)~~ personnel records for each employee of the manufacturer applicant that include an application for employment and a record of any disciplinary action taken;

(1517) employee safety and security training materials provided to each employee of the manufacturer applicant at the time of his or her initial appointment, to include:

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

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

~~(1618) an attestation that the manufacturer applicant will ensure that all persons who work at a facility of the manufacturer will be 18 years of age or older;~~

~~(19) a description of how the manufacturer applicant will utilize the electronic inventory tracking system required by the department;~~

~~(20) a written policy to ensure that no cross-contamination of cannabis occurs;~~

~~(21) copies of any applicable lease agreements for facilities to be used by the manufacturer applicant;~~

~~(22) an attestation that the manufacturer applicant has complied and will comply with all applicable state and local zoning, occupancy, licensing and building codes applicable to buildings to be utilized by the manufacturer;~~

~~(23) proof of prior approval by the New Mexico regulation and licensing department for the use of any compressed gas extraction equipment to be utilized by the manufacturer;~~

~~(24) an attestation that the manufacturer applicant will not use dimethylsulfoxide (DMSO) in the production of cannabis derived products, and will not possess DMSO on the premises of the manufacturer;~~

~~(25) a written statement of the days and hours that the manufacturer will operate;~~

~~(26) such other materials as the department may require.~~

~~C. **Packaging and labeling:** a **Prohibited additives:** A manufacturer applicant and a non-profit producer shall submit a description and sample of the opaque, child-resistant packaging of the concentrate or cannabis-derived distribute a product that is intended to be consumed by inhalation that includes polyethylene glycol, polypropylene glycol, vitamin E acetate, or medium chain triglycerides. A manufacturer and a non-profit producer shall utilize, including a label that shall contain:~~

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

~~(2) a batch number or code;~~

~~(3) a production date not combine nicotine, caffeine, or expiration date, including a "use by" or "freeze by" date for products capable of supporting the growth of infectious, toxigenic, or spoilage microorganisms;~~

~~(4) a description of the number of units of any other addictive substance with a usable cannabis contained within the product;~~

~~(5) instructions for use;~~

~~(6) warnings for use;~~

~~(7) instructions for appropriate storage;~~

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

~~(9) the name of the strain, . This prohibition shall not apply to the combination of cannabis with sugar, or a product facts, or a nutrition fact panel, and a statement that the product is for medical use by qualified patients, to be kept away from children, and not for resale; and~~

~~(10) the name of the department approved testing facility or facilities used for ingredient testing, and the type(s) of testing conducted in which caffeine is naturally occurring, such as coffee, tea, or chocolate.~~

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

~~**E. Identification cards:** **E. Identification cards:** An employee of an approved manufacturer shall carry their department issued employee identification card at all times during their work, and shall present the card to law enforcement officials and to department officials upon request. An employee who is unable to produce their department issued identification card upon request shall not remain on the licensed premises, and shall produce the card for the department's inspection prior to returning to the licensed premises. Identification cards issued by the department are the property of the department and shall be returned to the department upon termination of the holder's employment with the approved ~~laboratory~~ manufacturer, suspension, or revocation of approval by the department, or upon demand of the department.~~

F. Amended license:

(1) An approved manufacturer 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:

(a) change of location of the manufacturer's facilities, change of directors, change of ownership of the manufacturer's facilities, change of company name, and any physical modification or addition to the manufacturer's facilities; and

(b) substantial change to the manufacturer's methods for manufacturing cannabis-derived products, and any substantial change to the manufacturer's security plan.

(2) **Process for incomplete application for amended license:** In the event that an application for amended licensure is determined by the program to be incomplete, the program will specify the information or materials that remain to be submitted. If the manufacturer does not submit the requested information or material, and does not otherwise contact the department regarding the application, within thirty days of receiving notice of the deficiency, the application will be closed as incomplete, and the manufacturer will be required to resubmit the application in order to recommence the application process.

G. Inventory and sales equipment: The department may require a licensed manufacturer 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.

H. Reporting of theft to department: A manufacturer shall submit to the department notification of any theft, robbery, break-in, or security breach that occurs on the manufacturer's premises, no later than 10 calendar days after the manufacturer first becomes aware of the event. The description shall include a description of any property that was stolen or destroyed, and the quantity of any usable cannabis that was stolen.

I. Closure of applications period: The department may close the applications period during which applications for manufacturer licenses will be accepted and reviewed.

[7.34.4.1214 NMAC -- N, 2/27/2015; Rp. 7.34.4.12 NMAC, xx/xx/xxxx]

7.34.4.1315 STANDARDS FOR MANUFACTURE OF CANNABIS-DERIVED PRODUCTS: The following are minimum requirements for the manufacture of cannabis-derived products which shall apply to all manufacturers and licensed non-profit producers that manufacture cannabis-derived products:

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

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

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

~~(3) that all manufacturing is done indoors; with the exception that compressed gas extraction may occur outdoors in accordance with applicable standards of the New Mexico regulation and licensing department;~~

(4) that all manufacturing is conducted in a manner that does not allow cross-contamination from chemical or biological hazards;

(5) that manufacturing does not occur at a location that is within 300 feet of a school, church, or daycare center that existed within the 300-foot area before the non-profit producer or manufacturer became licensed to operate at the location;

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

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

(8) that hand-washing facilities are provided that are adequate, accessible, and conveniently located, and that they are furnished with running water at a suitable temperature; hand-washing facilities shall be located in ~~the facility~~ indoor production facilities, in ~~medical cannabis derived product preparation areas~~ restrooms, and ~~wherever~~ good sanitary practices require employees to wash or sanitize their

hands, and ~~provides~~shall be stocked with effective hand-cleaning and sanitizing preparations, and sanitary towel service or suitable drying devices;

~~(69)~~ **(69)** that all persons involved in preparing or handling medical cannabis or cannabis derived products at the manufacturing operation conform to hygienic practices while on duty, including:

~~(a) maintaining adequate personal cleanliness;~~

(a) maintaining adequate personal cleanliness;

~~(b) washing hands thoroughly in an adequate hand-washing area before starting work, and~~work, at any other time when the hands may have become soiled or contaminated, and both before putting gloves on and after removal of gloves;

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

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

~~(710)~~ **(710)** that there is sufficient space for placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations for production of medical cannabis derived products;

~~(811)~~ **(811)** that litter and waste are properly removed, and the operating systems for waste disposal are maintained in an adequate manner so that they do not constitute a source of contamination in areas where medical cannabis or cannabis derived products are exposed;

~~(912)~~ **(912)** that floors, walls, and ceilings are constructed in such a manner that they ~~may~~are washable, wipeable, and non-absorbent, and can be adequately cleaned, kept clean, and kept in good repair;

~~(10)~~ (13) that walls and ceilings remain free of water damage, and that fiberglass and other insulation material not be exposed;

~~(14)~~ **(14)** that there is adequate safety-type lighting in all areas where medical cannabis or cannabis derived products are processed or stored, and where equipment or utensils are cleaned;

~~(115)~~ **(115)** that the manufacturer provides adequate screening or other protection against the entry of pests; rubbish shall be disposed of so as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage, or breeding place for pests;

~~(1216)~~ **(1216)** that building, fixtures, and other physical facilities where cannabis derived products are manufactured are maintained in a sanitary condition;

~~(1317)~~ **(1317)** that all contact surfaces, including utensils and equipment used for preparation of cannabis derived products are cleaned and sanitized as frequently as necessary to protect against contamination;

~~(1418)~~ **(1418)** that all equipment and utensils used for preparation of cannabis derived products are designed and of such material and workmanship as to be adequately cleanable, and are properly maintained;

~~(1519)~~ **(1519)** that only environmental protection agency (EPA) registered sanitizing agents are used in manufacturing operations and that they are used in accordance with labeled instructions;

~~(1620)~~ **(1620)** that toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of medical cannabis or cannabis derived products;

~~(17)~~ (21) that any chemicals used for extraction in the manufacturing process be intended for such usage, and that they be of food or medical grade;

~~(22)~~ **(22)** that the water supply is sufficient for the operations intended and is derived from a source that is a regulated water system; private water supplies shall be from a water source that is capable of providing a safe, potable, and adequate supply of water to meet the manufacturing facility's needs;

~~(1823)~~ **(1823)** that plumbing shall be of adequate size and design, adequately installed, and maintained to carry sufficient quantities of water to required locations throughout the facility; and properly convey sewage and liquid disposable waste from the facility;

~~(1924)~~ **(1924)** that there are no cross-connections between the potable and waste water lines;

~~(2025)~~ **(2025)** that the manufacturer provide its employees with adequate, readily accessible, on-site toilet facilities that are maintained in a sanitary condition and good repair;

~~(2126)~~ **(2126)** that all operations in the receipt, inspection, transport, segregation, preparation, manufacture, packaging, and storage of medical cannabis or cannabis derived products are conducted in accordance with adequate security and sanitation principles;

~~(2227)~~ **(2227)** that medical cannabis or cannabis derived products that can support the rapid growth of undesirable microorganisms are stored and transported in a manner that prevents the growth of these microorganisms;

~~(2328)~~ that storage and transportation of ~~medical marijuana or usable~~ cannabis ~~derived products~~ ~~are accomplished~~ under conditions that will maintain security and protect medical cannabis or cannabis derived products against physical, chemical, and microbial contamination as well as against deterioration of the medical cannabis or cannabis derived product and the container;

~~(2429)~~ that current material safety data sheets are kept on the premises for all chemicals used, including but not limited to cleaning compounds, sanitizing agents, and pesticides; ~~and~~

~~(2530)~~ that extraction for the purpose of manufacturing concentrates is conducted in a closed system utilizing an oil extractor solvent such as N-butane or carbon dioxide or utilizing ethyl alcohol;

~~(31)~~ that all containers used for storage or transport of usable cannabis are washable, wipeable, and nonabsorbent;

~~(32)~~ that if alcohol is to be used for extraction, only food grade, non-denatured ethyl alcohol is used for that purpose;

~~(33)~~ that all weighting or measuring devices that are used in the production, distribution, or manufacture of usable cannabis be appropriately documented as having undergone certified registration and calibration that is in accordance with applicable requirements of the New Mexico department of agriculture;

~~(34)~~ that the manufacture of a cannabis derived product by a manufacturer from the cannabis material produced by a personal production license holder is recorded in an electronic tracking system specified by the department;

~~(35)~~ that the manufacturer or non-profit producer will prohibit its employees and contractors from being under the influence of drugs or alcohol in the workplace;

~~(36)~~ that the department is notified of any changes to the days or hours of business operation;

~~(37)~~ that staff who are tasked with conducting compressed gas extraction activities be appropriately trained in the use of extraction equipment, as well as safety and emergency procedures, by a qualified trainer, prior to beginning extraction activities;

~~(38)~~ that hemp, hemp extract, and hemp derived products (other than hemp paper and hemp seed oil) are not combined in any manner with usable cannabis that is intended to be sold or otherwise distributed in the medical cannabis program; and

~~(39)~~ that cannabis and cannabis derived products that are kept in manufacturing areas at all times be clearly segregated from hemp and hemp derived products.

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

C. Imprinting of certain usable cannabis products with universal THC symbol: A manufacturer and a licensed non-profit producer shall ensure that the universal New Mexico THC warning symbol, or a comparable symbol denoting THC content, is embossed or otherwise imprinted directly upon the following usable cannabis products that contain THC, prior to sale or distribution of any such product to a qualified patient or primary caregiver:

~~(1)~~ chocolate;

~~(2)~~ soft confections;

~~(3)~~ hard confections or lozenges; and

~~(4)~~ pressed pills and capsules

[7.34.4.1315 NMAC - N, 2/27/2015; Rp. 7.34.4.13 NMAC, xx/xx/xxxx]

7.34.4.1416 LABELING OF USABLE CANNABIS; DRUG INFORMATION SHEETS: A non-profit producer shall not sell or otherwise distribute to the public 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;

A. Packaging and labels not designed to appeal to children: A package containing ~~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 shall not display any content that reasonably appears to target minors, including but not limited to, cartoon characters or similar images. A product name or package shall not be modeled after a brand of product that is traditionally marketed toward children.

B. Labeling requirements: A label shall be securely affixed to all usable cannabis- product packages, prior to sale or distribution, that is in the format provided at Table 8, Sample Label for Usable Cannabis Products, that is conspicuous and unobstructed, and that uses a font that is clearly legible, not italicized, and is printed in no smaller than 1/16th of an inch. The cannabinoid content specified on a cannabis derived product contained within label shall be 90% or greater in accuracy. The label shall identify the following:

- (1) the product, as identified in department rules for names of the enrollment entities that produced and manufactured the product, respectively;
- (2) the name of the strain of qualified patients cannabis contained in the product;
- ~~E.~~(3) a manufacture date and an expiration date;
- (4) for dried, usable cannabis: the ~~quantity~~total of THC and CBD, both per serving and per package, which shall be expressed by percentage of weight;
- ~~F.~~(5) for concentrated cannabis derived product: -the ~~quantity~~total of THC and CBD, both per serving and per package, which shall each be expressed by weight in milligrams and by percentage of total weight;
- ~~G.~~(6) for non-concentrated cannabis derived product: the totals of THC and CBD, both per serving and per package, which shall each be expressed by weight in milligrams;
- (7) total product weight, expressed in milligrams, and if the product is in liquid form, total volume, expressed in milliliters;
- (8) the name of the strain;
- (9) the name of the department approved laboratories that analyzed the product or cannabis contained in the product in accordance with department rule;
- (10) for all products containing THC: the universal New Mexico THC warning symbol, the image file for which can be obtained from the department upon request, which shall be reproduced at a minimum size of 1/2 inch by 1/2 inch;
- (11) warnings for use that include at a minimum the statements, “Consumption of THC when pregnant, or by a mother who is breastfeeding, may adversely impact an infant’s development”, “Do not drive a vehicle or operate heavy machinery while under the influence of this product”, and “Keep out of reach of children”;
- (12) for all cannabis-derived products that contain THC and that are intended to be consumed by vaporization: a health warning that states in bolded text, “WARNING: Vaping THC has been associated with cases of severe lung injury, leading to difficulty breathing, hospitalization, and even death.”;
- (13) a sales barcode that is associated with the product and product batch;
- (14) a batch number or code that is associated with the product batch and that is recorded by the non-profit producer or manufacturer in the electronic tracking system specified by the department; and
- (15) instructions for use that are specific to the labeled product.

Table 8. Sample Label for Usable Cannabis Products		
Producer:		Manufacturer:
Name of strain:		Total units:
Net weight: mg	Manufacture/Production date: / /	Expiration date: / /
Laboratory Analysis		
PER SERVING:		PER CONTAINER:
THC: mg / % THC: %		THC: mg / % THC: %
CBD: mg / % CBD: %		CBD: mg / % CBD: %
Testing laboratory:		
Instructions for use:		
<p>WARNING: This product contains medical cannabis. Do not drive a vehicle or operate heavy machinery while under the influence of this product. Consumption of THC when pregnant, or by a mother who is breastfeeding, may adversely impact an infant’s development.</p> <p>WARNING: Vaping THC has been associated with cases of severe lung injury, leading to difficulty breathing, hospitalization, and even death.</p> <p>KEEP OUT OF REACH OF CHILDREN.</p>		



C. Drug information sheets: A non-profit producer shall generate a drug information sheet for every item of cannabis and cannabis derived product that is sold or distributed to a qualified patient or primary caregiver, and shall provide a copy of the drug information sheet to the qualified patient or primary caregiver at the time of sale or distribution, and upon request. A copy of a drug information sheet shall be provided to the department or its designee upon request. A drug information sheet shall be in the format provided at Table 9, Sample Label for Usable Cannabis Products, and shall use a font that is clearly legible, not italicized, and is printed in no smaller than 10 point type. The drug information sheet shall contain, at a minimum, the following:

(1) all of the content of the associated product label, as specified in this rule and identified in Table 8;

(2) a batch number or code that is associated with the cannabis used for the manufacture of the product, that is recorded by a non-profit producer in the electronic tracking system specified by the department;

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

(4) for dried, usable cannabis and edible cannabis products: the total of THC, THCA, CBD, and CBDA, both per serving and per package, which shall be expressed by weight in milligrams;

(5) for concentrated cannabis derived product: the totals of THC, THCA, CBD, and CBDA, both per serving and per package, which shall each be expressed by weight in milligrams and by percentage of total weight;

(6) for non-concentrated cannabis derived product: the total of THC, THCA, CBD, and CBDA, both per serving and per package, which shall each be expressed by weight in milligrams;

(7) a “best by” date or freeze date for products capable of supporting the growth of infectious, toxigenic, or spoilage microorganisms;

~~(8) H. instructions for use;~~

~~I. warnings for use;~~

~~J. instructions for appropriate storage;~~

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

~~L. the name of the strain, (9) complete list of product ingredients;~~

(10) 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 and a statement that the product is not for resale; and~~

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

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

(11) allergy warnings, including but not limited to information regarding whether the contents of the package were processed in any facility that also processes nuts.

Table 9. Sample Drug Information Sheet for Usable Cannabis Products
Cannabis Facts
Product name:
Product strain:
Producer of cannabis:
Manufacturer of cannabis product:
Net product weight:
Total units:
Manufacture date:

<u>Product expiration date:</u>	
<u>Batch number or code for manufactured product:</u>	
<u>Batch number or code for cannabis:</u>	
<u>Instructions for use:</u>	
<u>Instructions for storage:</u>	
<u>Nutrition facts:</u>	
<u>Product ingredients:</u>	
<u>Allergy warnings:</u>	
<u>Laboratory Analysis</u>	
<u>PER SERVING:</u>	<u>PER CONTAINER:</u>
<u>THC: mg / % THC: %</u>	<u>THC: mg / % THC: %</u>
<u>THCA: mg / % THCA %</u>	<u>THCA: mg / % THCA %</u>
<u>CBD: mg / % CBD: %</u>	<u>CBD: mg / % CBD: %</u>
<u>CBDA: mg / % CBDA %</u>	<u>CBDA: mg / % CBDA %</u>
<u>Testing laboratory:</u>	
<u>WARNING: This product contains medical cannabis. This product is for medical use by qualified patients only. This product is not for resale.</u> <u>Do not drive a vehicle or operate heavy machinery while under the influence of this product. Consumption of THC when pregnant, or by a mother who is breastfeeding, may adversely impact an infant’s development.</u> <u>WARNING: Vaping THC has been associated with cases of severe lung injury, leading to difficulty breathing, hospitalization, and even death.</u> <u>KEEP OUT OF REACH OF CHILDREN.</u>	
	

D. Expiration date: An expiration date that is identified on a usable cannabis product label shall not be modified, removed, or obscured. In the event that an expiration date specified on a usable cannabis product label has passed, the product shall be wasted in accordance with the terms of this rule and deducted from inventory in the electronic tracking system specified by the department.

E. Failure to comply with packaging or labeling requirements: If a non-profit producer does not comply with any packaging or labeling requirement of this rule, the department may immediately suspend sales and distribution of any such non-compliant product, may order the recall of any such product, may order the relabeling of any such product, and may pursue disciplinary action in accordance with this rule.

[7.34.4.1416 NMAC - N, 2/27/2015; A, 2/29/2016; Rp. 7.34.4.14 NMAC. xx/xx/xxxx]

7.34.4.1517 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) quantity of THC and CBD; and
- (5) 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, 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)(17) documented proof of required initial and continuing demonstrations of capability, in accordance with this rule;
- (18) proof that no buildings to be used by the applicant are located within 300 feet of any school, church, or daycare center; or alternatively, proof that any school, church, or daycare center that is located within 300 feet of a building to be used by the applicant did not occupy that location prior to the applicant initially seeking to become licensed to operate at the location;
- (19) an attestation that the laboratory will not operate in any location within 300 feet of a school, church or daycare center; and
- (20) 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-director or designee. 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 and approved manufacturers 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-director or designee, 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 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: An employee of an approved laboratory shall carry their department issued employee identification card at all times during their work, and shall present the card to law enforcement officials and to department officials upon request. An employee who is unable to produce their department issued identification card upon request shall not remain on the licensed premises, and shall produce the card for the department's inspection prior to returning to the licensed premises. 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.~~ **H. Reporting of theft to department:** A laboratory shall submit to the department notification of any theft, robbery, break-in, or security breach that occurs on the laboratory's premises, no later than 10 calendar days after the laboratory first becomes aware of the event. The description shall include a description of any property that was stolen or destroyed, and the quantity of any usable cannabis that was stolen.

~~_____I.~~ **I. 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~~60 days prior to expiration.

~~_____J.~~ **J. Amended license:**

(1) An approved laboratory 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:

(a) change of location of the laboratory's facilities, change of directors, change of ownership of the laboratory's facilities, change of company name, and any physical modification or addition to the laboratory's facilities; and

(b) substantial change to the laboratory's standard operating procedures or substantial change to the types of tests to be conducted.

(2) Process for incomplete application for amended license: In the event that an application for amended licensure is determined by the program to be incomplete, the program will specify the information or materials that remain to be submitted. If the laboratory does not submit the requested information or material, and does not otherwise contact the department regarding the application, within thirty days of receiving notice of the deficiency, the application will be closed as incomplete, and the laboratory will be required to resubmit the application in order to recommence the application process.

~~_____K.~~ **K. 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.

[7.34.4.1517 NMAC - N, 2/27/2015; A, 2/29/2016; Rp. 7.34.4.15 NMAC, xx/xx/xxxx]

7.34.4.1618 DEPARTMENT-APPROVED TESTING LABORATORIES; GENERAL OPERATIONAL REQUIREMENTS:

A. Receipt of test samples: An approved laboratory may receive test samples of cannabis or cannabis derived products from any licensed producer, qualified patient or primary caregiver, and shall apply the testing standards of this rule, including the testing parameters, action levels, reporting levels, and other criteria identified in Tables 1 through 6, to determine whether a sample passes a given test.

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

- (1) accepted test sample types;
- (2) minimum test sample size;
- (3) recommended test sample container;
- (4) test sample labeling;
- (5) transport and storage conditions, such as refrigeration, as appropriate;
- (6) other requirements, such as use of preservatives, inert gas, or other measures designed to protect sample integrity; and
- (7) creation of chain of custody documentation for each sample.

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

- (1) record the receipt of every test sample received, the record of which shall include:
 - (a) the name and contact information of the licensed producer that was the source of the sample;
 - (b) an appropriately specific description of the sample;
 - (c) the date of receipt of the sample;
 - (d) a statement of the quantity (weight, volume, number, or other amount) of the sample; and

~~(e) a unique sample identifier for the sample.~~

~~(e) a batch number or code that is associated with the product batch and that is recorded by the non-profit producer or manufacturer in the electronic tracking system specified by the department.~~

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

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

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

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

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

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

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

~~(b) destroyed in accordance with the wastage requirements of this rule.~~

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

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

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

H. Equipment:

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

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

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

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

I. Reagents, solutions, and reference standards:

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

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

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

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

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

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

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

J. Analysis: An approved laboratory shall:

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

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

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

(a) sample preparation;

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

(c) instrument setup, as applicable;

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

(e) data acquisition; and

(f) calculation of results.

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

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

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

K. Recording of analytical data:

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

(2) In automated data collection systems, the individual responsible for direct data input shall be identified at the time of data input. Any change in ~~automated data entries~~ an entry shall be made so as not to ~~void or delete~~ obscure the original entry, shall indicate the reason for such change, ~~shall be dated~~, and shall ~~identify~~ be dated and signed or initialed at the responsible individual time of the change. A corrective action report (CAR) shall accompany such change and shall be made available to the department, a non-profit producer, and a manufacturer upon their request for up to two years after the analysis is completed.

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

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

(b) the data meet any data quality requirements such as for accuracy, precision,

linearity, etc.;

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

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

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

L. Data storage:

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

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

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

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

(c) in a manner that prevents unauthorized alteration.

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

N. Data reporting:

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

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

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

~~(c) the unique sample identifier;~~

~~(c) the batch number or code that is associated with the product batch and that is recorded in the electronic tracking system specified by the department;~~

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

(e) date on which analysis occurred;

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

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

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

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

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

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

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

~~**P. Drugs and alcohol:** A laboratory shall prohibit its employees and contractors from being under the influence of drugs or alcohol in the workplace.~~

~~**Q. Failures to meet testing requirements:** Repeated failures by a laboratory to comply with the testing requirements of department rule may result in disciplinary action against the laboratory.~~

~~[7.34.4.16]8 NMAC - N, 2/27/2015; Rp. 7.34.4.16 NMAC, xx/xx/xxxx]~~

7.34.4.177.34.4.19 DEPARTMENT-APPROVED TESTING LABORATORIES; INSTRUMENTATION; INITIAL AND CONTINUING DEMONSTRATIONS OF CAPABILITY:

A. Mycotoxin test instrumentation: A laboratory shall utilize HPLC, LCMS, or LCMSMS instrumentation to test for the presence of mycotoxins in usable cannabis and shall analyze for mycotoxins at a concentration as low as 1 µg/kg (ppb). Mycotoxin testing shall be conducted in accordance with the requirements of Table 2, Mycotoxins Testing Requirements.

B. Residual solvents test instrumentation: A laboratory shall utilize gas chromatography – flame ionization detector (GC-FID), gas chromatography tandem photoionization detector/flame ionization detector (GC-PID/FID), or GCMS instrumentation to test for the presence of residual solvents and shall analyze for residual solvents at a concentration as low as 2µg/g (ppm). Residual solvent testing shall be conducted in accordance with the requirements of Table 3, Residual Solvent Testing Requirements.

C. Potency test instrumentation: A laboratory shall utilize HPLC or LCMS instrumentation to test for potency in usable cannabis and shall analyze usable cannabis in accordance with the provisions at Table 4 Potency Testing Requirements.

D. Heavy metals test instrumentation: A laboratory shall utilize Inductively coupled plasma mass spectrometry (ICP-MS) or flow injection mercury system (FIMS) instrumentation to test for the presence of heavy metals in usable cannabis and shall analyze for heavy metals at a concentration as low as 0.2 µg/g (ppm) for lead (Pb) and cadmium (Cd), as low as 1.0 µg/g (ppm) for arsenic (As) and 0.1 µg/g (ppm) for mercury (Hg). Heavy metals testing shall be conducted in accordance with the requirements of Table 5, Heavy Metals Testing Requirements.

E. Pesticide test instrumentation: A laboratory shall utilize high performance liquid chromatography (HPLC), gas chromatography mass spectrometry (GCMS), liquid chromatography - mass spectrometry (LCMS), or liquid chromatography with tandem mass spectrometry (LCMSMS) instrumentation to test for the presence of pesticides in usable cannabis and shall analyze for pesticides at a concentration as low as 100 µg/kg (ppb). Pesticide testing shall be conducted in accordance with the provisions of Table 6, Pesticide Testing Requirements.

F. Initial and continuing demonstrations of capability required: A laboratory or laboratory applicant shall submit to the department an initial demonstration of capability (IDC) for every test identified in this rule that the laboratory or applicant intends to conduct. A laboratory shall submit a continuing demonstration of capability (CDC) annually as part of the laboratory's application for renewal of licensure. The IDC shall be submitted to the department prior to the laboratory or laboratory applicant conducting tests pursuant to this rule. Each IDC and CDC shall describe how quality control samples (negative control samples, positive control samples, low-positive controls, and instrument performance check controls), internal standards, and surrogate standards are to be assessed to determine if the data from an analytical batch are acceptable. The laboratory shall maintain a documented procedure for performing every IDC and CDC. The laboratory shall retain documentation verifying the IDC and CDC for each test required by this rule and make this documentation available to the department upon request. The IDC and CDCs shall follow the same parameters as outlined in the requirements of this rule. Every IDC and CDC that is submitted shall be conducted within one year of application (excluding mycotoxins).

(1) An IDC shall be reconducted and resubmitted to the department:

(a) whenever there is a change in method;

(b) whenever an instrument has been moved;

(c) whenever a new instrument is installed; and

(d) whenever the method has not been performed by the laboratory or sampler

within a 12-month period.

(2) Every IDC and CDC shall include the following elements:

(a) **Demonstration of method calibration:** The calibration range shall use at least five calibration points consisting of five different concentration levels of target compounds. The calibration range shall include a low calibration point equal to, or less, than the required minimum reporting level for each targeted compound. The calibration range shall include a calibration point equal to the action level for each targeted compound (mycotoxins and residual solvents). A laboratory or laboratory applicant shall provide the equation and the type of curve fit used for the calibration range, and the percent relative standard deviation or the goodness of fit. The percent relative standard deviation shall be less than 20%, or the goodness of fit (correlation coefficient) shall be 0.995 or better.

(b) **Demonstration of method accuracy and precision:** A laboratory or laboratory applicant shall supply the quantitation data for five positive control samples analyzed by its testing method utilizing a median or mid-level calibration concentration. A laboratory or laboratory applicant shall calculate and provide the calculated mean (average) result and the standard deviation. The percent relative standard deviation shall be less than 15%, and the mean shall be within 15% of the expected concentration. For laboratories using GC-FID, GC-PID/FID, or GCMS platforms for residual solvents, the percent relative standard deviation may be within 20%, and the mean may be within 20%, of the expected concentration for the targeted compounds propane, n-butane, isobutane, and methanol.

(c) **Demonstration of method detection limit:** A laboratory or laboratory applicant shall supply the quantitation data of seven low-level or minimum action level positive control samples. The concentration of these low-level positive control samples is set equal to the lowest calibration point the laboratory uses. These data are then used to calculate a standard deviation, which is then used to calculate method detection limit (MDL) using the following equation: $(3.14267 \times \text{standard deviation} = \text{method detection limit})$. The calculated method detection limit for each targeted mycotoxin and residual solvent shall be less than the required method

reporting level. For potency testing, quantitation values of all the seven low-level positive controls fall within 50% to 150% of the expected concentration for the cannabinoids THC, THCA, CBD, and CDBA.

(d) **Demonstration of low system background:** A laboratory or laboratory applicant shall supply the analytical data of at least three negative control samples that do not contain any mycotoxins, residual solvents, or cannabinoids. For mycotoxins and residual solvents, the quantitation values shall be less than the minimum detection limit or a non-detect. For potency testing, the quantitation values shall be less than one-third of the value of the method reporting level.

(e) **Demonstration of analyte identification:** A laboratory that uses, and a laboratory applicant than intends to use, HPLC, GC-FID, or GC-PID/FID instrumentation shall supply analytical data where each targeted compound is analyzed as a single compound giving it its characteristic retention time. A laboratory that uses, and a laboratory applicant than intends to use, GCMS, LCMS, or LCMSMS instrumentation shall supply analytical data with the characteristic mass spectrum of each targeted compound.

G. **Use of internal standards:** A laboratory shall utilize an internal standard chemical compound in the instrumental analysis (testing methods) of cannabinoids, residual solvents, mycotoxins, heavy metals, and pesticides, which are collectively referred to as the tested analytes. The internal standard compound shall be used to determine the characteristic relative chromatographic retention times of these tested analytes to ensure proper analyte identifications (qualification) whenever mass spectral data are not obtained by an instrument. The internal standard compound shall be used to determine the relative instrument response of the tested analytes to ensure the proper measurement of analyte concentrations (quantitation).

H. **Reporting results:** A laboratory shall use no more than two significant figures to report a positive result. A laboratory shall report a non-detect of an analyte as less than the laboratory's minimum reporting level. A laboratory shall also report a pass or fail evaluation with the reported result. A pass evaluation is assigned to a reported result less than the analytes action level listed. A fail evaluation is assigned to a reported result equal to or greater than the action level for each given analysis, consistent with the requirements of this rule.
[7.34.4.19 NMAC – N. xx/xx/xxxx]

7.34.4.20 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, 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~~ applicant 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; or alternatively, proof that any school, church, or daycare center that is located within 300 feet of a building to be used by the applicant did not occupy that location prior to the applicant initially seeking to become licensed to operate at the location;

(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; and

~~C.~~ (24) an attestation that the courier will not transport cannabis across state lines.

C. Application fee: A courier applicant shall submit to the program with each initial application and renewal application for continued approval a non-refundable application fee of one-thousand-five-hundred dollars (\$1,500), payable to the medical cannabis program.

D. 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 qualified patients, primary caregivers, other non-profit producers, approved manufacturers and approved laboratories; 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;

(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 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 or entity who is not identified by the licensed non-profit producer as an intended, authorized recipient;

(6) at the time of delivery, an approved courier shall verify the recipient's identity by requiring presentation of the recipient'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 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;

(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; ~~and~~

~~D(12) an approved courier shall not, when transporting usable cannabis to a qualified patient or primary caregiver, utilize a delivery vehicle that advertises or otherwise displays signage, logos, or symbols that would indicate that the vehicle is used for the transport of cannabis.~~

E. 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~~their department issued employee identification card at all times ~~that the person transports cannabis during their work,~~ and shall present the card to law enforcement officials and to department officials upon request. An employee who is unable to produce their department issued identification card upon request shall not remain on the licensed premises, and shall produce the card for the department's inspection prior to returning to the licensed premises. 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.

EF. 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.~~ **G. Amended license:**

(1) An approved courier 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:

(a) change of location of the courier's facilities, change of directors, change of ownership of the courier's facilities, change of company name, and any physical modification or addition to the courier's facilities; and

(b) substantial change to the courier's methods for storing, transporting and delivering cannabis-derived products, and any substantial change to the courier's security plan.

(2) **Process for incomplete application for amended license:** In the event that an application for amended licensure is determined by the program to be incomplete, the program will specify the information or materials that remain to be submitted. If the courier does not submit the requested information or material, and does not otherwise contact the department regarding the application, within thirty days of receiving notice of the deficiency, the application will be closed as incomplete, and the courier will be required to resubmit the application in order to recommence the application process.

H. Reporting of theft to department: A courier shall submit to the department notification of any theft, robbery, break-in, or security breach that occurs on the courier's premises, no later than 10 calendar days after the courier first becomes aware of the event. The description shall include a description of any property that was stolen or destroyed, and the quantity of any usable cannabis that was stolen.

I. Drugs and alcohol: A courier shall prohibit its employees and contractors from being under the influence of drugs or alcohol in the workplace.

J. Inventory and sales equipment: The department may require a licensed courier to utilize specified equipment, software, and services for purposes of tracking distribution, inventory, and other information, and for the purpose of reporting that information to the department of health.

K. 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.

GL. 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.

[7.34.4.1620 NMAC - N, 2/27/2015; A, 2/29/2016; Rp. 7.34.4.16 NMAC, xx/xx/xxxx]

7.34.4.1821 QUALIFIED PERSONAL PRODUCTION APPLICATION AND LICENSURE REQUIREMENTS:

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

B. A qualified patient may obtain no more than one personal production license, which license may be issued for production to occur either indoors or outdoors in no more than one single location.

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

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

- (1) applicable non-refundable fee;
- (2) a description of the single indoor or outdoor location that shall be used in the production of cannabis;
- (3) if the location is on property that is not owned by the applicant: a written statement from the property owner or landlord that grants to the applicant permission to grow cannabis on the premises;
- (4) a written plan that ensures that the cannabis production shall not be visible from the street or other public areas;
- (5) a written acknowledgement that the applicant will ensure that all cannabis, cannabis-derived products and paraphernalia is accessible only by the applicant and their primary caregiver (if any), and kept secure and out of reach of children;
- (6) a description of any device or series of devices that shall be used to provide security and proof of the secure grounds; and
- (7) a written acknowledgement of the limitations of the right to use and possess cannabis for medical purposes in New Mexico.

[7.34.4.1821 NMAC - Rp, 7.34.4.9 NMAC, 2/27/2015; A, 8/27/2019; Rp. 7.34.4.18 NMAC, xx/xx/xxxx]

7.34.4.1922 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 cannabis plants that the non-profit entity has been approved to produce as well as an inventory of usable cannabis that reflects current patient needs;

(2) a production plan that includes the non-profit entity's plan for the growth, cultivation, and harvesting of medical cannabis;

(3) a written set of distribution criteria for qualified patients or primary caregivers appropriate for cannabis services that describes the method by which and locations at which distribution will occur;

(4) a complete written description of the means that the non-profit entity shall employ to safely dispense cannabis and cannabis-derived products to qualified patients and qualified patients' primary caregivers;

(5) an attestation that qualified patients shall not be permitted to consume cannabis or cannabis-derived products on the entity's property, unless the consumption occurs in a department approved cannabis consumption area;

(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; and manufacture of cannabis-derived products (as applicable);

(2) proof that the facilities are not within 300 feet of any school, church, or daycare center; and/or alternatively, proof that any school, church, or daycare center that is located within 300 feet of a building to be used by the applicant did not occupy that location prior to the applicant initially seeking to become licensed to operate at the location; 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;

(f) robbery awareness and conflict de-escalation training for all employees;

(g) general food safety training.

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

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

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

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

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

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

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

L. ~~Local ordinance~~State and local laws: A licensed non-profit producer shall comply with all applicable ~~local ordinances~~state and local laws regarding construction, occupancy, and operation of a facility or building, including but not limited to zoning, occupancy, licensing, and building codes.

[7.34.4.1922 NMAC - Rp, 7.34.4.8 & 10 NMAC, 2/27/2015; A, 2/29/2016; A, 8/27/2019]

; Rp. 7.34.4.2022 NMAC, xx/xx/xxxx]

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

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

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

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

[7.34.4.2023 NMAC - Rp, 7.34.4.11 NMAC, 2/27/2015; Rp. 7.34.4.20 NMAC, xx/xx/xxxx]

7.34.4.2124 RECALLS OF USABLE CANNABIS:

A. All non-profit producers and approved manufacturers shall establish and implement written procedures for recalling usable cannabis and products that have been sold or otherwise distributed to qualified patients, primary caregivers, or other cannabis establishments. Recall procedures shall be made available for the department's inspection upon request. The recall procedures shall identify:

(1) The circumstances in which a recall will be conducted, including but not limited to circumstances involving the mislabeling of products and the contamination of products;

(2) Personnel responsible for implementing the recall procedures;

(3) Procedures for notification of all customers who have, or reasonably could have, obtained an affected product, including communication and outreach via media, as appropriate;

(4) Procedures for notification of any other cannabis establishment that supplied or received the recalled product;

(5) Instructions to be provided to qualified patients, primary caregivers, and cannabis establishments for the return or destruction of the recalled product;

(6) Procedures for the collection and wastage (as may be required by this rule) of any recalled product, which shall meet the requirements of this section.

B. All recalled products that are intended to be destroyed shall be wasted in accordance with the wastage requirements of this rule.

C. The licensee shall notify the department of any recall within 24 hours of initiating the recall.

D. The department may order the immediate recall of a usable cannabis product if it deems such action necessary to protect public health and safety.

[7.34.4.24 NMAC - N, xx/xx/xxxx]

7.34.4.25 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~~director 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~~director 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~~director or designee may submit a written request for a record review. To be effective, the written request shall:

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

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

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

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

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

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

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

E. Final determination:

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

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

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

F. Judicial review: Except as otherwise provided by law, there shall be no right to judicial review of a decision by the program ~~manager~~director or designee, the administrative review committee, or the secretary. [7.34.4.24+25 NMAC - Rp, 7.34.4.12 NMAC, 2/27/2015; Rp. 7.34.4.21 NMAC, xx/xx/xxxx]

7.34.4.2226 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 approved entity, or the employees or contractors of a licensed producer or approved entity, does not relieve the producer, approved entity, employee, or contractor from criminal prosecution or civil penalties for activities not authorized in this rule and the act.

B. Locations of production ~~and~~, distribution, and manufacture: Production of medical cannabis and distribution of medical cannabis to qualified patients or their primary caregivers shall take place at locations (or, with respect to distribution, categories of locations) described in the non-profit producer's production and distribution plan approved by the department, and shall not take place at locations that are within 300 feet of any school, church, or daycare center. For purposes of this rule, delivery to the residence of a qualified patient or primary caregiver shall not be deemed "distribution".

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

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

E. Revocation of registry identification card, licensed primary caregiver card, license to produce or distribute: Violation of any provision of this rule may result in disciplinary action, in accordance with this rule.

[7.34.4.2226 NMAC - Rp, 7.34.4.14 NMAC, 2/27/2015; Rp. 7.34.4.22 NMAC, xx/xx/xxxx]

7.34.4.2327 CANNABIS CONSUMPTION AREAS:

A. General provisions: The smoking, vaporizing, and ingestion of medical cannabis products by qualified patients is permitted within cannabis consumption areas, designated by the department, that are located on the premises of licensed non-profit producers. Cannabis consumption areas may only be operated by licensed non-profit producers, at medical cannabis dispensary locations designated by the department. Alcohol is prohibited in cannabis consumption areas. A licensed non-profit producer that operates a cannabis consumption area shall

comply with all applicable state and local laws, including but not limited to zoning, occupancy, licensing, and building codes. Additionally, a licensed non-profit producer that operates a designated cannabis consumption area shall:

- (1) Restrict access to the cannabis consumption area to qualified patients and their primary caregivers and authorized personnel of the non-profit producer;
- (2) Ensure that consumption of cannabis in the cannabis consumption area is not visible from any public place or from outside the cannabis consumption area; and
- (3) Require that qualified patients who consume cannabis in a cannabis consumption area either leave the non-profit producer's premises with a designated driver or utilize other lawful means of transportation from the non-profit producer's premises.

B. Application; operations plan: A licensed non-profit producer shall apply for and obtain prior approval from the department before operating a cannabis consumption area. The licensed non-profit producer shall include an operations plan with its application that includes the following:

- (1) Operating hours of the cannabis consumption area;
- (2) Plan for limiting access to qualified patients and primary caregivers access and verification process;
- (3) Security plan addressing overall security measures, including but not limited to plans for video surveillance, fire safety, public disturbances, refusal of service, and emergency evacuation;
- (4) Plan for ensuring that only qualified patients, primary caregivers, and authorized staff can access cannabis consumption areas;
- (5) Plan for educating patients and primary caregivers about the dangers of driving under the influence of cannabis;
- (6) Plan concerning disposal of wasted cannabis and cannabis-related paraphernalia;
- (7) Plan concerning measures to limit potential allergic reactions by qualified patients and primary caregivers who visit the cannabis consumption area;
- (8) Plan to ensure that qualified patients who are minors are accompanied by their primary caregiver at all times while on the premises of a cannabis consumption area;
- (9) Attestation that access to cannabis consumption areas will be limited to qualified patients and their primary caregivers and authorized personnel of the non-profit producer;
- (10) Attestation that consumption of cannabis in the cannabis consumption area will not be visible from any public place or from outside the cannabis consumption area;
- (11) Attestation that the non-profit producer will require that qualified patients who consume cannabis in a cannabis consumption area either leave the non-profit producer's premises with a designated driver (who shall be identified to the non-profit producer by the qualified patient or primary caregiver) or utilize other lawful means of transportation from the non-profit producer's premises; and
- (12) Such additional information or materials as the department may require.

C. Amended license: The licensed non-profit producer shall apply for amended licensure, and shall obtain approval from the department, at least 30 days prior to implementing any change of location of a cannabis consumption area or any substantial change to any portion of the non-profit producer's cannabis consumption area operations plan.

[7.34.4.27 NMAC – N, xx/xx/xxxx]

7.34.4.28 RECIPROCITY: Beginning July 1, 2020, an individual who holds proof of authorization to participate in the medical cannabis program of another state of the United States, the District of Columbia, a territory or commonwealth of the United States or a New Mexico Indian nation, tribe or pueblo may lawfully purchase and possess cannabis, provided that the quantity of cannabis does not exceed the reciprocal limit identified in this section.

A. Reciprocal participation:

- (1) General requirements:** A reciprocal participant:
 - (a) may participate in the medical cannabis program in accordance with department rules;
 - (b) shall not be required to comply with the registry identification card application and renewal requirements established pursuant to this section and department rules;
 - (c) shall at all times possess proof of authorization to participate in the medical cannabis program of another state, the District of Columbia, a territory or commonwealth of the United States or a

New Mexico Indian nation, tribe or pueblo and shall present proof of that authorization when purchasing cannabis from a licensee; and

(d) shall register with a licensed non-profit producer for the purpose of tracking sales to the reciprocal participant in an electronic system specified by the department.

(2) Minors: In the event that a reciprocal participant is a minor, a licensed non-profit producer shall not sell or transfer cannabis to the minor, but may sell or transfer cannabis to a parent or legal guardian of the minor who holds proof of authorization to purchase cannabis on the minor's behalf that was issued by another state of the United States, the District of Columbia, a territory or commonwealth of the United States or a New Mexico Indian nation, tribe or pueblo.

B. Reciprocal limit: A reciprocal participant may collectively possess within any three-month period a quantity of usable cannabis no greater than 230 total units. For purposes of department rules, this quantity is deemed the reciprocal limit. (For ease of reference: 230 units is equivalent to 230 grams, or approximately eight ounces, of dried usable cannabis plant material.)

C. Registration; verification; tracking: A licensed non-profit producer shall require the submittal of a reciprocal participant's contact information for registration purposes, to include the individual's full name, date of birth, mailing address, and the enrollment number specified in the individual's medical cannabis program enrollment card (if applicable); and shall record that information in an electronic tracking system specified by the department. The licensed non-profit producer shall confirm the accuracy of a reciprocal participant's contact information prior to each transaction. A licensed non-profit producer that registers a reciprocal participant or that sells or transfers cannabis or a cannabis product to a reciprocal participant shall first verify the reciprocal participant's identity by viewing the individual's proof of authorization from the other state, territory or tribe, and also viewing the reciprocal participant's government-issued photo identification card. A licensed non-profit producer that sells or otherwise transfers cannabis or a cannabis product to a reciprocal participant shall track the sale or transfer using an electronic system specified for that purpose by the department.

D. Refusal of service: A non-profit producer that reasonably suspects that either a person's proof of authorization or identification card is falsified may refuse to dispense cannabis to cannabis to that individual.

E. Informational materials: At the time of a sale or transfer of cannabis to a reciprocal participant, a non-profit producer shall provide informational materials to the reciprocal participant that include, at a minimum, a notice of the time and quantity limits for reciprocity under this section, and a notice concerning state and federal prohibitions against the transport of cannabis across state and international boundaries.

[7.34.4.28 NMAC – N, xx/xx/xxxx]

7.34.4.29 ENFORCEMENT OF PARENTAL RESPONSIBILITY ACT:

A. The medical cannabis program's approval of an employee of a non-profit producer or an approved entity to work for such producer or approved entity may be suspended, and a request for an individual to be approved to work for such a producer or approved entity may be denied, for failure of the approved employee or prospective employee to comply with a judgment and order for child support issued by a district or tribal court or a subpoena or warrant relating to paternity or child support proceedings, as provided in the Parental Responsibility Act, Section 40-5A-1 et seq., NMSA 1978.

B. Procedures for enforcement of the Parental Responsibility Act:

(1) List of obligors: The New Mexico human services department (HSD) will issue to the medical cannabis program a certified list of obligors (meaning persons who have been ordered to pay child support pursuant to a judgment and order for support issued by a district or tribal court) not in compliance with their judgment and order of support or a subpoena or warrant relating to paternity or child support proceedings.

(2) Notice of noncompliance: Upon determination by the medical cannabis program that the name and social security number of an approved employee or prospective employee of a non-profit producer or an approved entity appear on the certified list of obligors, the medical cannabis program shall notify the approved employee or prospective employee in writing. The medical cannabis program may send a copy of the notice of noncompliance to the non-profit producers or approved entities affiliated with the approved employee or prospective employee. The notice shall state that the medical cannabis program intends to suspend the approved employee's approval to work for the non-profit producer or approved entity, or deny the prospective employee's approval to work for the non-profit producer or approved entity, unless the approved employee or prospective employee, within thirty days of the date that the written notice is issued, provides to the medical cannabis program a certified statement from the human services department that he or she is in compliance with a judgment and order for support or subpoenas or warrants relating to paternity or child support proceedings.

(3) Notice of contemplated action: If the approved employee or prospective employee of a non-profit producer or approved entity does not provide to the medical cannabis program the certified statement of compliance from HSD within thirty days of the date that the written notice is issued, the medical cannabis program shall issue a notice of contemplated action to the approved employee or prospective employee, stating that the medical cannabis program has grounds to suspend or deny the individual's authorization to work for the non-profit producer or approved entity, and that the medical cannabis program shall take such action unless the individual mails a letter (certified mail, return receipt requested) requesting a hearing within 20 days after service of the notice requesting a hearing, or provides the bureau, within 30 days of receipt of the notice of contemplated action, a statement of compliance from HSD. The medical cannabis program may send a copy of the notice of contemplated action to the non-profit producers or approved entities affiliated with the approved employee or prospective employee.

(4) Disputes regarding findings of noncompliance: If the approved employee or prospective employee disagrees with the finding of non-compliance, or wishes to come into compliance, the approved or prospective employee shall contact the HSD child support enforcement division.

(5) Hearings: The hearing process of this rule part shall apply to hearings conducted pursuant to this section; provided that, in any such hearing, the following standards shall also apply:

(a) The presence of an individual's name and social security number on the HSD list of obligors is deemed conclusive evidence of an individual's noncompliance that requires the medical cannabis program to deny or withdraw approval of an individual to work for a non-profit producer or approved entity, unless the individual provides the medical cannabis program with a certified statement of compliance, in which case the medical cannabis program shall be precluded from taking further action under this section;

(b) When an action is taken against an approved employee or prospective employee of a non-profit producer or approved entity because the individual is not in compliance with a judgment and order of support or a subpoena or warrant relating to paternity or child support proceedings, the order shall state that the individual's approval to work for a non-profit producer or approved entity shall be reinstated upon presentation to the medical cannabis program of a certified statement of compliance from HSD; and

(c) The secretary may also include in the order any other conditions necessary to comply with requirements for reapplication and re-issuance of licensure, including, but not limited to, requiring payment of a surcharge fee of \$50, in addition to any other applicable fees.
[7.34.4.29 NMAC – N, xx/xx/xxxx]

7.34.4.30 MONITORING AND CORRECTIVE ACTIONS:

A. Monitoring:

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

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

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

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

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

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

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

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

(1) **Access:** The department and its agents shall have reasonable access to the ~~sales and other~~ financial records of a licensed non-profit producer manufacturer, laboratory, or courier, including but not limited to sales records and data from point of sale systems, and shall be granted immediate access to inspect or copy those records upon request. A patient shall be granted reasonable access to a licensed non-profit producer's or manufacturer's sales records for that patient upon request.

(2) **Audit:** A licensed non-profit producer shall submit the results of an annual audit to the department no later than 90 days after the end of each fiscal year of the licensed non-profit. For the purposes of this section, the fiscal year of a non-profit producer shall be the 12 month cycle identified by the producer in its filings with the New Mexico taxation and revenue department. The annual audit shall be conducted by an independent certified public accountant; the costs of any such audit shall be borne by the private entity. Results of the annual audit shall be forwarded to the medical cannabis program ~~manager~~director or designee. The department may also periodically require, within its discretion, the audit of a non-profit producer's financial records by the department.

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

- (a) Number of qualified patients and primary caregivers who purchased usable cannabis;
- (b) Total number of retail transactions;
- (c) Average amount (in units) purchased per retail transaction;
- (d) Number of units provided without charge;
- (e) Number of cannabis plants in production, including mature plants and seedlings;
- (f) Number of cannabis plants harvested;
- (g) Total yield of usable cannabis harvested from cannabis plants (in grams);
- (h) Average yield per plant (in grams);
- (i) Amount of cannabis (in grams) sold by wholesale;
- (j) Amount of cannabis (in grams) purchased by wholesale;
- (k) Number of live cannabis plants (including clones) and cannabis seeds sold;
- (l) Amount of dried cannabis leaves and flowers in stock;
- (m) Average price per gram of dried cannabis leaves and flowers;
- (n) Total amount of dried cannabis leaves and flowers sold (in units);
- (o) Total sales of dried cannabis leaves and flowers (in dollars and units);
- (p) Amount of cannabis derived products in stock (in units);
- (n) Total amount of cannabis derived products sold (in units);
- (o) Total sales of cannabis derived products (in dollars and units);
- (p) Amount of gross receipts tax paid to the New Mexico department of taxation

and revenue;

(q) All quality testing reports, to be included as attachments; and
~~(r) A detailed description of any thefts, robberies, break ins or security breaches that occurred, including a description of any property that was stolen or destroyed, and the quantity of any usable cannabis that was stolen; and~~

~~(s)~~ (r) Such additional information as the department may request.

C. Corrective action:

(1) If violations of requirements of this rule are cited as a result on the basis of a violation that is directly observed in the course of a monitoring ~~or~~visit at an approved location, or on the basis of a review of financial records, the licensed producer, manufacturer, laboratory, or courier shall be provided with an official written report of the findings within seven business days following the monitoring visit or the review of financial records.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[7.34.4.2330 NMAC - Rp, 7.34.4.15 NMAC, 2/27/2015; A, 7.34.4.23 NMAC, 8/27/2019; Rp. 7.34.4.23 NMAC, xx/xx/xxxx]

7.34.4.2431 DISCIPLINARY ACTIONS AND APPEAL PROCESS:

~~A.~~ **A. Notice of disciplinary action:** The department may issue notice of an immediate disciplinary action, as specified in this rule, or notice of contemplated disciplinary action. Notice shall be served upon a licensee's contact person of record. Notice shall be served via certified U.S. postal mail. A notice shall be deemed to have been served on the date borne by the return receipt showing delivery or the last attempted delivery of the notice or decision to the addressee or refusal of the addressee to accept delivery of the notice or decision.

B. Grounds for disciplinary action: Disciplinary action may be taken against a producer-applicant, a licensed producer, a manufacturer-applicant or approved manufacturer, a laboratory applicant or approved laboratory, or an approved courier or courier-applicant. Disciplinary action may include revocation, suspension, or denial of an application, license, or department approval, monetary penalties, ~~and other action~~immediate suspensions and revocations in accordance with this rule, and other action. Disciplinary actions may be imposed in any combination, and the actions described in this paragraph, including suspension and monetary fines, are not exclusive of one another. Disciplinary action may be imposed for:

(1) A major violation implicating public safety, including:

(a) failure to comply with or satisfy any provision of this rule that implicates public safety;

(b) diversion, inversion, or attempted diversion or inversion, of cannabis or a cannabis-derived product, as determined by the department;

(c) threatening or harming a patient, a medical practitioner, or an employee of the department;

- (d) intentionally destroying, damaging, altering, removing or concealing evidence of a violation under this rule, attempting to do so, or asking or encouraging another person to do so;
- (e) deliberately purchasing usable cannabis, cannabis-derived products or cannabis plants from out of state or outside the legal medical cannabis system; or
- (f) other conduct that shows willful or reckless disregard for health or safety;
- (2) A major violation not implicating public safety, including:
 - (a) failure to pay a required monetary penalty;
 - (b) failure to comply with the department’s requested access to premises or materials;
 - (c) failure to allow or impede a visit by authorized representatives or designees of the department;
 - (d) falsification or misrepresentation of any material or information submitted to the department;
 - (e) failure to adhere to any acknowledgement, verification, or other representation made to the department;
 - (f) failure to submit or disclose information required by this rule or otherwise requested by the department;
 - (g) failure to correct any violation of this rule cited as a result of a review or audit of financial records or other materials, or cited as a result of a monitoring visit or site inspection;
 - (h) a pattern of non-major license violations;
 - (i) noncompliance with tax obligations as determined by a taxation regulatory authority;
 - (j) exceeding the plant limit of the license; and
- (3) Any other violation, including:
 - (a) failure to comply with or satisfy any provision of this rule that does not implicate public safety;
 - (b) failure to take a video recording of the ~~destruction~~wastage of usable cannabis, in accordance with this rule; and
 - (c) selling or transferring to a qualified patient or primary caregiver a quantity of usable cannabis greater than the maximum amount permitted by department rule.

BC. Fines: Disciplinary actions against a licensed non-profit producer, approved manufacturer, approved laboratory, or approved courier may include the imposition of monetary penalties, which may be assessed by the department in the amount of:

- (1) up to \$50,000 for each major violation implicating public safety;
- (2) up to \$20,000 for each major violation not implicating public safety;
- (3) up to \$5,000 for each other violation.

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

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

D.E. **Closure of applications period:** A hearing may not be requested by a person or entity whose application for licensure is denied solely on the basis that the applicable applications period is closed.

F. **Timing and content of request for hearing:** The appellant shall ~~file~~email the request for hearing within 30 calendar days of the date ~~the action is taken or that~~ the notice of contemplated action is received, or in the case of an immediate action, within 30 days of the action. The request shall:

- (1) be properly addressed to the medical cannabis program;
- ~~(2)~~ **(2)** be mailed to the medical cannabis program via certified U.S. postal mail;
- (3)** state the requestor's name, address, and telephone number(s); and
- (3A)** include a statement of the issue(s) that the appellant considers relevant to the review of the action.

E.G. **Hearing process:**

- (1) All hearings held pursuant to this section shall be conducted by a hearing officer appointed by the secretary.
- (2) Hearings shall be conducted in Santa Fe, NM or, with the consent of the parties, in another location.
- (3) Due to federal and state confidentiality laws, hearings held pursuant to this section that concern qualified patients, patient-applicants, licensed producers or producer-applicants, shall be closed to the public. Portions of hearings may further be closed to prevent the disclosure of confidential information.
- (4) The hearing shall be recorded on audiotape or other means of sound reproduction.
- (5) Any hearing provided for in this rule may be held telephonically, with the consent of the parties.

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

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

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

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

- (1) all pleadings, motions, and intermediate rulings;
- (2) evidence and briefs received or considered;
- (3) a statement of matters officially noticed;
- (4) offers of proof, objections, and rulings thereon;
- (5) proposed findings and conclusions; and
- (6) any action recommended by the hearing examiner.

H.K. **Audio recording:** A party may request a copy of the audio recording of the proceedings.

H.L. **Procedures and evidence:**

- (1) A party may be represented by a person licensed to practice law in New Mexico or a non-lawyer representative, or may represent himself or herself.
- (2) The rules of evidence as applied in the courts do not apply in these proceedings. Any relevant evidence shall be admitted. Irrelevant, immaterial, or unduly repetitious evidence may be excluded.
- (3) The experience, technical competence, and specialized knowledge of the hearing examiner, the department or the department's staff may be used in the evaluation of evidence.
- (4) An appellant's failure to appear at the hearing at the date and time noticed for the hearing shall constitute a default.

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

- (1) the appellant shall present an opening statement and the department may present an opening statement or reserve the statement until presentation of the department's case;
- (2) after the opening statements, if made, the appellant shall present its case;

- (3) upon the conclusion of the appellant's case, the department shall present its case;
- (4) upon conclusion of the appellee's case, the appellant may present rebuttal evidence; and
- (5) after presentation of the evidence by the parties, the parties may present closing

argument.

~~LN~~. 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.

~~MO~~. 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.

~~NP~~. Telephonic hearings:

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

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

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

~~OQ~~. Recommended action and final decision:

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

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

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

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

[7.34.4.~~2431~~ NMAC - Rp, 7.34.4.16 NMAC, 2/27/2015; A, 7.34.4.24, 8/27/2019; Rp. 7.34.4.24 NMAC, xx/xx/xxxx]

7.34.4.~~2532~~ EXEMPTION FROM STATE CRIMINAL AND CIVIL PENALTIES:

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

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

C. In accordance with the Public School Code, Chapter 22 NMSA 1978, and the Lynn and Erin Compassionate Use Act at Subsection G of Section 26-2B-4 NMSA 1978, the department hereby deems New Mexico public schools, school districts, local school boards, locally-chartered charter schools, state-chartered charter schools, and governing bodies of state-chartered charter schools to be licensees, and designated school personnel (including designated employees and volunteers of the foregoing licensees) to be licensee representatives, authorized within the licensees' licensure to possess and store cannabis and cannabis derived products on behalf of

qualified students, and to administer cannabis and cannabis derived products to qualified students, in school settings. The department deems the licensees and licensee representatives to be entitled to immunity from arrest, prosecution or penalty, in any manner, for activities conducted within the licensees' licensure and in accordance with the Public School Code.

D. A reciprocal participant shall not be subject to arrest, prosecution or penalty in any manner for the possession of or the medical use of cannabis if the quantity of cannabis does not exceed the limit identified by department rule.

[7.34.4.2532 NMAC - Rp, 7.34.4.17 NMAC, 2/27/2015; A, 7.34.4.25, 8/27/2019; Rp. 7.34.4.25 NMAC, xx/xx/xxxx]

7.34.4.267.34.4.33 CLOSURE OF A NON-PROFIT PRODUCER OR AN APPROVED ENTITY: A non-profit producer, manufacturer, laboratory, or courier that anticipates ceasing its business operations shall notify the medical cannabis program no later than 30 calendar days prior to closure. Any such non-profit producer or approved entity shall post public notice of the anticipated closure in any and all locations of the producer or approved entity that are accessible to the public, including but not limited to dispensary locations, at least fourteen days prior to the closure. Any unused medical cannabis that is held by a non-profit producer or approved entity on behalf of another licensee (such as cannabis that is owned by a non-profit producer and held by a manufacturer) shall be returned to its owner. Cannabis that is otherwise held by a licensee shall, prior to the licensee's closure, be surrendered to either state law enforcement or local law enforcement, destroyed by the licensee in accordance with the wastage standards of this rule, or donated to patients via a licensed non-profit producer, and the licensee shall submit documentation of the event to the department.

[7.34.4.33 NMAC – N, xx/xx/xxxx]

7.34.4.34 PERSONAL PRODUCTION LICENSE CONFIDENTIALITY: Personal production license holders and applicants: The department shall maintain a confidential file containing the names, addresses, and telephone numbers of the persons who have either applied for or received a personal production license (PPL). Individual names of PPL producers and PPL producer-applicants 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; and

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

[7.34.4.2634 NMAC - Rp, 7.34.4.18 NMAC, 2/27/2015; A, 7.34.4.26 NMAC, 2/29/2016; Rp. 7.34.4.26 NMAC, xx/xx/xxxx]

7.34.4.2735 STORAGE AND DISPOSAL OF CANNABIS BY LICENSED PRODUCERS:

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

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

[7.34.4.2735 NMAC - Rp, 7.34.4.19 NMAC, 2/27/2015]

:Rp. 7.34.4.2827 NMAC, xx/xx/xxxx]

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

[7.34.4.~~2836~~ NMAC - Rp, 7.34.4.20 NMAC, 2/27/2015; Rp. 7.34.4.28 NMAC, xx/xx/xxxx]

7.34.4.~~2937~~ **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.~~2937~~ NMAC - Rp, 7.34.4.21 NMAC, 2/27/2015; Rp. 7.34.4.29 NMAC, xx/xx/xxxx]

HISTORY OF 7.34.4 NMAC:

History of Repealed Material:

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

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

NMAC History:

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

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