New Mexico Department of Health
Proposed Adoption of the New Rule 7.35.2 Medical Psilocybin Producer and Laboratory Requirements
Hearing Date: April 24th, 2026

LIST OF EXHIBITS

1.	New Chapter Approval 7.35.2 NMAC Medical Psilocybin Producer and Laboratory Requirements
2.	Proposed New Rule 7.35.2 NMAC Medical Psilocybin Producer and Laboratory Requirements
3.	Notice of Public Hearing
4.	Affidavit of Publication – Albuquerque Journal
5.	Affidavit of Publication – NM Register
6.	Letter Appointing Hearing Officer
7.	Affidavit of Notice to the Public
8.	List of Anticipated Revisions
9.	Public Comments

EXHIBIT 1

NEW MEXICO
State Records Center and Archives
COMMISSION OF PUBLIC RECORDS
Your Access to Public Information

February 24, 2026

VIA ELECTRONIC MAIL TO: Christopher Woodward, Deputy General Counsel, DOH

Christopher Woodward, General Counsel
Department of Health (DOH)
PO Box 26110
Santa Fe, New Mexico 87502-6110

Dear Mr. Woodward:

I am in receipt of your letter dated February 24, 2026, with regard to the request for the approval of new Chapter name. Your request is approved and this information has been recorded in the Administrative Law Division's master listing as:

TITLE 7 HEALTH
CHAPTER 35 MEDICAL USE OF PSILOCYBIN

If you have any questions, please contact Pamela Lujan y Vigil, Senior Management Analyst at (505) 476-7990.

Sincerely,

Rick Hendricks
Digitally signed by Rick Hendricks
Date: 2026.02.24 11:38:22 -07'00'

Rick Hendricks, PhD
State Records Administrator
cc: File

TITLE 7 HEALTH
CHAPTER 35 MEDICAL PSILOCYBIN
PART 2 PRODUCER AND LABORATORY REQUIREMENTS

7.35.2.1 ISSUING AGENCY: New Mexico Department of Health.
[7.35.2.1 NMAC - N, xx/xx/2026]

7.35.2.2 SCOPE: All persons, whether natural or legal entities, that apply to transact, or that transact, business in New Mexico as a psilocybin producer or psilocybin testing laboratory, their owners, agents, and assignees.
[7.35.2.2 NMAC - N, xx/xx/2026]

7.35.2.3 STATUTORY AUTHORITY: This rule is promulgated pursuant to the following statutory authorities: the New Mexico Department of Health Act, Subsection E of Section 9-7-6 NMSA 1978; and the Medical Psilocybin Act, Section 26-2D-7, NMSA 1978.
[7.35.2.3 NMAC - N, xx/xx/2026]

7.35.2.4 DURATION: Permanent.
[7.35.2.4 NMAC - N, xx/xx/2026]

7.35.2.5 EFFECTIVE DATE: xx/xx, 2026, unless a later date is cited at the end of a section.
[7.35.2.5 NMAC - N, xx/xx/2026]

7.35.2.6 OBJECTIVE: The objective of this rule is to adopt rules governing the issuance of permits to producers and laboratories to operate within the New Mexico medical psilocybin program, established pursuant to the Medical Psilocybin Act at Sections 26-2D-1 through -11, NMSA 1978. The rule sets standards for applications for producer and laboratory permits, and standards for the operations of producers and laboratories, including but not limited to specifying: products allowed to be sold or otherwise distributed by producers; restrictions on the application of pesticides and other adulterants to psilocybin products; requirements for implementation and usage of a department-approved traceability system; testing requirements; wastage requirements; sanitation requirements; and transportation requirements. This rule also establishes a procedure for disciplinary actions to be taken against permits, and a process for administrative appeals from disciplinary actions and proposed disciplinary actions.
[7.35.2.6 NMAC - N, xx/xx/2026]

7.35.2.7 DEFINITIONS:

A. Definitions beginning with "A":

(1) "Actual control" means the ability to:

(a) direct the policies, management, and personnel of a permittee;

(b) exert authority over strategic priorities, capital allocations, acquisitions, and divestments of a permittee; or

(c) control a majority of voting rights of a permittee.

(2) "Administration session" means the therapeutic session combined with the administration of psilocybin.

(3) "Adulterate" means to use or incorporate a substance that contaminates a psilocybin product and that creates a risk to public health.

(4) "Analytes" means a substance whose chemical constituents are being identified and measured.

(5) "Appellant" means a person who requests a hearing to contest an immediate or proposed disciplinary action.

(6) "Approved location" means a location approved by the department for psilocybin administration sessions.

B. Definitions beginning with "B": "Board" means the medical psilocybin advisory board.

C. Definitions beginning with "C":

(1) "Capsule" means a small soluble pill, tablet or container that contains homogenized psilocybin material.

(2) **"Certification"** means an approval issued by the department to a clinician or a practitioner to provide medical services to qualified patients.

(3) **"Clinician"** means an approved health care provider licensed in New Mexico who holds a certification from the department to provide medical services to qualified patients.

(4) **"Compliance notification"** means a notification of noncompliance with a regulatory requirement that is issued to a psilocybin producer or psilocybin testing laboratory.

(5) **"Compound"** means to prepare psilocybin to tailor dosage, and includes grinding and powdering psilocybin mushrooms, as well as the creation of psilocybin capsules.

(6) **"Convert"** means converting psilocybin mushrooms into a homogenized lot.

(7) **"Cultivation"** means the growing, harvesting, drying, and handling of psilocybin-producing mushrooms.

(8) **"Cultivation batch"** or **"batch"** means a quantity of unharvested spores, fruiting body, or mycelium that is grown together under the same conditions, that may contain fungi that originates from diverse spores or mycelial tissue.

D. Definitions beginning with "D": "Department" means the department of health.

E. Definitions beginning with "E": "Expiration date" means a date determined by a producer after which an associated psilocybin product will not retain optimal quality.

F. Definitions beginning with "F":

(1) **"Facility"** means any building, space, or grounds licensed for the cultivation, harvesting, drying, storage, or preparation of psilocybin-producing fungi or psilocybin products.

(2) **"Flush"** means the fruiting body of psilocybin mushrooms harvested at the same time from a growing medium.

(3) **"Fruiting bodies"** means the spore producing organs of the fungi.

(4) **"Fungi"** is any member of the group of eukaryotic organisms that includes microorganisms such as yeasts and molds, as well as the more familiar mushrooms.

G. Definitions beginning with "G":

(1) **"Genuine ownership"** means an ownership interest in an applicant or a permittee that is evidenced by record ownership in which the owner, regardless of the amount of capital or assets that the owner contributes to the applicant or permittee, enjoys the customary incidents of ownership and shares in the profits and losses of the permittee proportionate to the percentage of the owner's interest in the permit.

(2) **"Growth medium"** or **"substrate"** means the underlying base layer, surface, or nutrient rich substance where fungal growth occurs.

(3) **"Guide"** an individual who has completed training and education approved by the department to be able to assist practitioners during the administration sessions and who has been registered with the department.

H. Definitions beginning with "H":

(1) **"Harvest"** means to remove, collect, or gather, fruiting bodies of mushrooms containing psilocybin.

(2) **"Harvest lot"** means the fruiting bodies of mushrooms cultivated and harvested at the permitted location.

(3) **"Homogenization date"** means the date a harvest lot is homogenized.

(4) **"Homogenized"** means dried fruiting bodies that have been mixed by powdering or other techniques which uniformly distribute psilocybin throughout the product.

(5) **"Homogenized lot"** means a quantity of psilocybin mushrooms identified by a producer that is cultivated and dried under the same conditions, and harvested within a specified time period at the same location within permitted premises.

I. Definitions beginning with "I":

(1) **"Information notification"** means a notification providing information regarding relevant updates and alerts that is issued to a psilocybin producer or psilocybin testing laboratory;

(2) **"Inoculate"** means the process of introducing psilocybin spores of mycelium into growth medium.

(3) **"Input"** means material utilized in growing medium for growing psilocybin mushrooms, including but not limited to soil, grain, woodchips, water, nutrients, and other materials.

J. Definitions beginning with "J": [RESERVED]

K. Definitions beginning with "K": [RESERVED]

L. Definitions beginning with "L": [RESERVED]

M. Definitions beginning with "M":

(1) "Manufacture" or **"process"** means to harvest, dry, compound, convert, or package into pills, capsules, or sachets of homogenized powder, and label mushrooms and products containing psilocybin.

(2) "Medical services" means services provided to a patient in an approved setting before, during and after the ingestion of psilocybin and includes a preparation session, an administration session and an integration session.

(3) "Mycelium" means the fungal threads or hyphae of psilocybin containing mushrooms.

(4) "Mushroom" is the fleshy, spore-bearing fruiting body of a fungus.

N. Definitions beginning with "N": [RESERVED]

O. Definitions beginning with "O": [RESERVED]

P. Definitions beginning with "P": [RESERVED]

(1) "Package" means to enclose, wrap, or seal psilocybin products.

(2) "Permit" means the authorization issued by the department to a person to operate as a psilocybin producer or psilocybin testing laboratory under this part.

(3) "Permit-applicant" means a person who has applied for a permit to operate as a psilocybin producer or psilocybin testing laboratory.

(4) "Permittee" means a psilocybin producer or psilocybin testing laboratory that holds a permit issued by the department.

(5) "Person" means a natural person, corporation, partnership, limited liability company, association, and any other business or organization that is capable of entering into contracts, owning property, and suing or being sued.

(6) "Potency" means the level of psilocybin and analytes in a sample of a batch, lot, or product which is measured and expressed in metric units.

(7) "Practitioner" means an individual who is a licensed healthcare professional who is certified by the department to provide medical psilocybin integrative therapy, supervise guides, and who has completed department required trainings.

(8) "Product lot" means the same type of product that has been created from a homogenized lot.

(9) "Program" means the medical use of psilocybin program.

(10) "Psilocybin" means the naturally occurring psychedelic compound 4-phosphoryloxy-N, N-dimethyltryptamine, also known as 4-PO-DMT, and its pharmacologically active metabolite psilocin, 4-hydroxy-N, N-dimethyltryptamine, found in certain mushrooms, but does not include synthetic or synthetic analogs of psilocybin.

(11) "Psilocybin material" means psilocybin mushrooms, mycelium, and derived material that naturally contain psilocybin.

(12) "Psilocybin mushroom" means a fungus that naturally contains psilocybin.

(13) "Psilocybin producer" or **"producer"** means a person who has a permit from the department to grow and harvest or prepare psilocybin from psilocybin-producing mushrooms, including to compound, convert, process or manufacture psilocybin products directly or indirectly from psilocybin mushrooms and to package or repackage or label or relabel the products.

(14) "Psilocybin product" means psilocybin material that is intended for sale or distribution to a qualified patient.

(15) "Psilocybin testing laboratory" or **"laboratory"** means a facility permitted by the department to test psilocybin products for potency and contaminants in accordance with this rule.

(16) "Psilocybin waste" means:

(**a**) Partially consumed products;

(b) Byproducts of cultivation, harvesting, processing, or other production of products;

(c) Products disposed or to be disposed by a producer or laboratory; and

(d) Products designated for disposal by the department due to contamination, expiration, or which do not follow the requirements for production and administration.

Q. Definitions beginning with "Q":

(1) "Qualified patient" or **"patient"** means a patient whose clinician has judged the patient to be a medically appropriate candidate for the use of medical psilocybin based on being diagnosed with a qualifying condition.

(2) "Qualifying condition" includes:

(a) major treatment-resistant depression;
(b) posttraumatic stress disorder;
(c) substance use disorders;
(d) end-of-life care; and
(e) other conditions approved by the department;

R. Definitions beginning with "R": "Recall" means to remove a medical psilocybin product from the medical psilocybin market by contacting persons to whom the product was sold or otherwise distributed and having the product returned to the producer for destruction;

S. Definitions beginning with "S": "Satchet" means a small, sealed package or pouch of homogenized psilocybin mushrooms.

T. Definitions beginning with "T":

(1) "Testing sample" means the unit of psilocybin mushrooms or products being tested.

(2) "Traceability system" means the department-approved system that is used to track psilocybin mushrooms and products from inoculation to end use.

U. Definitions beginning with "U": "Unique identification number" means the most recent unique number assigned by traceability for a psilocybin product that may include cultivation batches, harvest lots, homogenized lots, product lots, and testing samples.

V. Definitions beginning with "V": [RESERVED]

W. Definitions beginning with "W": [RESERVED]

X. Definitions beginning with "X": [RESERVED]

Y. Definitions beginning with "Y": [RESERVED]

Z. Definitions beginning with "Z": [RESERVED]

[7.35.2.7 NMAC - N, xx/xx/2026]

7.35.2.8 PERMIT APPLICATION REQUIREMENTS:

A. General requirements: An applicant for a producer or laboratory permit shall provide to the department and shall maintain the following records:

(1) business license in the state of New Mexico;
(2) proof of registration of the business with New Mexico secretary of state;
(3) proof of registration of the business with New Mexico taxation and revenue department;
(4) certificate of occupancy;
(5) proof of fire code compliance;
(6) electrical and HVAC inspection reports;
(7) proof of compliance with applicable city and county planning/zoning requirements;
(8) proof that facility is within the geographical boundaries of New Mexico;
(9) proof of ownership of the facility or written approval from the owner to cultivate psilocybin on the premises;
(10) conditional use permits where applicable (e.g., city of Albuquerque raw food permit);
(11) an attestation that all psilocybin and psilocybin products will be produced or tested (as applicable to the permit type) only within the state of New Mexico and will not be transported beyond the borders of the state of New Mexico; and
(12) such additional documentation as the department may reasonably request to ensure compliance with this rule or other applicable laws, regulations, or ordinances.

B. Additional producer application requirements: An applicant for a producer permit shall additionally provide to the department and maintain food safety training certificates for employees.

C. Additional laboratory application requirements: An applicant for a psilocybin testing laboratory permit shall additionally provide to the department and maintain the following records:

(1) A license or permit from New Mexico regulation and licensing department - cannabis control division with:
(a) Proof of current approval to operate as a cannabis testing laboratory in New Mexico;
(b) Standard operating procedures for sampling and testing of psilocybin;
(c) An initial demonstration of capabilities for each of the tests required by this rule; or

(2) Proof of current ISO/IEC 17025 or NELAC/TNI accreditation, with:
(a) Standard operating procedures for sampling and testing of psilocybin; and

(b) An initial demonstration of capabilities for each of the tests required by this rule.

D. Changes in location, equipment, or status: A permittee shall apply for and shall obtain an amended permit prior to implementing any substantial structural modification to its permitted location. Additionally, a permittee shall notify the department of any change to registrations, licenses, permits, certifications, and any equipment alterations or acquisitions that substantially affect the production process.

[7.35.2.8 NMAC - N, x/xx/2026]

7.35.2.9 GENERAL PERMITTEE REQUIREMENTS:

A. Compliance with applicable laws: A permittee shall comply with all applicable state, tribal, and local laws, regulations, and ordinances, including requirements concerning agriculture, environmental health, building and occupancy, fire safety, zoning, and worker safety.

B. Dual ownership prohibited: A person who holds an ownership interest in a permittee shall not hold an ownership interest in any other permittee.

C. Permits non-transferable: A permit shall not be transferred by sale, assignment, or otherwise. A permit that is transferred shall be invalid.

D. Transfer of actual control prohibited: An applicant or permittee shall not transfer actual control of the applicant or permittee to any person using a management, consulting, or intellectual property agreement, or by any other means. A transfer of actual control shall invalidate an associated permit.

E. Nominee, straw, and proxy ownership prohibited: A person shall not apply for or hold a permit if any ownership interest in the permit is nominal or without the benefits and risks of genuine ownership or control.

F. Record of financial interests: Permittees shall create and maintain complete lists of all individuals and legal entities that hold a financial interest in the permittee or the operations of the permittee, including contact information for each individual or entity and a description of their financial interest. Applicants and permittees shall provide the information required by this section to the department within 15 calendar days of the department's written request for such information. If a legal entity holds a financial interest in the permittee or the permittee's operations within the medical psilocybin program, the following individuals within the legal entity shall be deemed to also hold a financial interest:

(1) For limited partnerships, each general partner in the limited partnership;

(2) For limited liability companies, each manager and managing member of the limited liability company;

(3) For for-profit corporations, each principal officer of the corporation; and

(4) For non-profit entities, each principal officer of the entity.

[7.35.2.9 NMAC - N, x/xx/2026]

7.35.2.10 GENERAL PRODUCER REQUIREMENTS:

A. A producer shall:

(1) Only cultivate, manufacture, and possess psilocybin and psilocybin products on the producer's permitted premises, and shall not transport psilocybin outside the state of New Mexico.

(2) Use equipment, counters and surfaces for post-harvest processing that are food-grade and do not react adversely with any solvent being used.

(3) Construct and maintain floors, walls, ceilings, counters and surface areas in a manner that reduces the potential development of microbials, molds, and unintended fungi.

(4) Maintain the licensed premises in a manner that is free from conditions that may result in contamination of psilocybin products and that is suitable for safe and sanitary operations.

(5) Store all psilocybin products in a secured, locked area, including psilocybin products that require refrigeration.

(6) Associate every harvest lot, homogenized lot, and product lot with a unique identification number and enter this information into the traceability system.

(7) Only sell psilocybin or psilocybin products to other producers and to practitioners; and only otherwise distribute psilocybin or psilocybin products to medical psilocybin testing laboratories, or to department employees for testing in accordance with this rule.

(8) Immediately discontinue operations and notify the department in the event of an imminent health hazard that could result in contamination of psilocybin products.

[7.35.2.10 NMAC - N, x/xx/2026]

7.35.2.11 ALLOWED PSILOCYBIN PRODUCTS:

A. A producer shall not manufacture psilocybin by chemical synthesis.

B. A producer shall not adulterate a psilocybin product and shall not sell or otherwise distribute an adulterated psilocybin product.

C. Psilocybin products shall be homogenized prior to being made available for sale or distribution.

D. Psilocybin products not authorized by this rule are prohibited and may not be manufactured, nor possessed, by any permittee.

[7.35.2.11 NMAC - N, x/xx/2026]

7.35.2.12 PESTICIDES AND OTHER ADULTERANTS PROHIBITED:

A. Producers are prohibited from applying pesticides to fungi or growing medium.

B. A producer shall not add to psilocybin products, substrates, growing medium, or packaging any chemical, drug, plant, or substance that has the effect of increasing potency, intoxicating effect, duration of effect, toxicity or potential for excessive use.

C. A producer shall document in the traceability system the growing medium and inputs utilized by the producer.

D. A producer shall not use inputs that are adulterated, shall destroy adulterated products, and shall document their destruction in the traceability system.

E. Psilocybin products that are intended for product development and that will not be made available for consumption shall be labeled in bold, capital letters, in a font size no smaller than 12 points, "NOT FOR CONSUMPTION".

[7.35.2.12 NMAC - N, x/xx/2026]

7.35.2.13 PRODUCER POLICIES AND PROCEDURES: A producer shall create, and shall at all times maintain on its premises, policies and procedures that include but are not limited to:

A. instructions for making each psilocybin product, including ingredients, and inputs;

B. the procedure for making each harvest lot or harvest lots homogenous;

C. procedures for conducting safety checks prior to commencing production of psilocybin products;

D. procedures for cleaning all equipment, counters and surfaces;

E. procedures for preventing growth of pathogenic organisms and toxin formations;

F. procedures for proper handling and storage of any solvent or other chemical used in cleaning and in production in accordance with material safety data sheets and other applicable laws;

G. procedures for proper disposal of any waste produced during processing in accordance with applicable laws, rules, and ordinances;

H. procedures for appropriate use of any necessary safety or sanitary equipment; and

I. emergency procedures to be followed in case of fire, chemical spill or other emergencies.

[7.35.2.13 NMAC - N, x/xx/2026]

7.35.2.14 PACKAGING AND LABELING; PRODUCT INFORMATION DOCUMENT:

A. Packaging requirements: A producer shall comply with the following packaging requirements for all psilocybin products:

(1) A producer shall utilize packaging for a psilocybin product that is intended for sale or distribution that protects the product from contamination and excessive moisture, and that does not impart any toxic or harmful substance.

(2) Packaging shall not display any untruthful or misleading content.

(3) Packaging shall not feature a design that is attractive to minors; and

(4) A label shall be printed or otherwise affixed on the psilocybin product package that shall:

(a) contain all required information in a legible font at least eight points;

(b) be written in English (though it may also be written in additional languages);

(c) be unobstructed and clearly visible;

(d) contain the producer's business name and permit number;

(e) identify the type of product contained in the packaging (e.g., homogenized mushroom powder);

(f) identify the species name and cultivar(s) of fungi contained in the psilocybin product;

(g) identify the net quantity of the package contents using the metric system of measurement;

(h) identify the potency of psilocybin analytes contained in the product, expressed in milligrams, and calculated using laboratory test results, including:

(i) total psilocybin equivalent; and

(ii) total potential psilocin;

(i) identify a unique identification number of the product lot;

(j) identify the expiration date of the psilocybin product;

(k) include the statement, "Keep out of the reach of children"; and

(l) a logo designated by the department that is no smaller than 1/2 inch by 1/2 inch, indicating the product contains psilocybin;

B. Product information document: A producer shall generate and make available to qualified patients and practitioners a product information document, in printed and electronic form, that lists the following information in English in 12-point font or larger:

(1) all of the information required to be contained on the product label;

(2) a statement regarding the number of years the producer's business has been established in New Mexico and a statement declaring the state and country of residency, including length of time of residency, of any individual who owns or has invested in the company;

(3) results of all laboratory tests and re-tests conducted on homogenized lots and product lots;

(4) the type and composition of the growth medium used, including type of grain, soil, compost, and other inputs;

(5) date of manufacture or processing of the final product, including date of homogenization;

(6) list of all active and inactive ingredients in descending order of predominance by weight or volume;

(7) list of potential major food allergens which might be contained in the product or in the growth medium;

(8) intended use and directions for use;

(9) a description of how the product should be stored to maintain quality and freshness;

(10) the statement: "This product is not approved by the FDA to treat, cure, or prevent any disease. The FDA has not evaluated this product for safety, effectiveness, or quality. There may be long term adverse health effects from consumption of psilocybin, including additional risks for women who are or may become pregnant or are breastfeeding."

(11) the statement, "The risks, benefits, drug interactions, and effects of psilocybin are not fully understood. Individual results may vary";

(12) the statement, "Do not drive a motor vehicle or operate machinery while under the use of psilocybin";

(13) the telephone number for the New Mexico poison and drug information center; and

(14) the telephone number for the New Mexico crisis and access line.

C. A practitioner shall provide the product information document to the patient prior to administration of the applicable psilocybin product.

D. A practitioner shall, upon request, make reasonable efforts to provide a translation of the product information document to languages other than English and in an accessible format.

[7.35.2.14 NMAC - N, x/xx/2026]

7.35.2.15 GENERAL TRACKING REQUIREMENTS: In addition to any requirements specific to tracking within each permit type, all producers shall meet minimum requirements.

A. Tracking psilocybin: Producers shall track cultivation batches, harvest lots, homogenized lots, product lots, and psilocybin product inventory using the traceability system specified by the department, in accordance with the following:

(1) each cultivation batch, homogenized lot, and product lot shall be assigned a unique identification number in the traceability system;

(2) cultivation batches shall not be transferred in their entirety to another producer; and

(3) producers are prohibited from removing an assigned unique identification number.

B. Tracking testing results: Medical psilocybin laboratories shall record the results of all required testing of psilocybin samples or products using the traceability system.

C. **Additional information to be recorded:** A producer shall ensure the following data is timely and accurately recorded in the traceability system:

(1) a complete inventory of all cultivation batches, harvest lots, homogenized lots, product lots, and psilocybin products in the possession, control or ownership of the producer;

(2) any changes to the producer's inventory;

(3) when psilocybin material is converted to waste;

(4) the reason any psilocybin material is converted to waste;

(5) when psilocybin waste is destroyed;

(6) any theft of psilocybin related batches, lots, or products;

(7) all sales records of products;

(8) results of all testing mandated by the department; and

(9) the county and municipality, as applicable, where the psilocybin or psilocybin product was harvested, otherwise cultivated, manufactured, tested, sold to other producers, sold to practitioners, and disposed of or destroyed.

[7.35.2.15 NMAC - N, x/xx/2026]

7.35.2.16 IMPLEMENTATION AND ADMINISTRATION OF TRACEABILITY SYSTEM:

A. Operational account: A producer and a laboratory may apply for an account and department training once they receive a permit from the department. A producer and a laboratory shall activate a traceability system account and shall ensure the account is functional prior to operating or exercising any privilege of a permit.

B. System administrator required: Each producer and laboratory shall designate at least one individual as a traceability system administrator.

C. Additional users: A producer and a laboratory may designate additional individuals as traceability system users. The producer or laboratory shall ensure that all individuals who are granted account access are trained by a traceability system administrator in the use of the traceability system.

D. System training: A producer and a laboratory or its designee shall attend and successfully complete all required traceability system training provided by the department.

E. Continuing education: The department may require additional continuing education for a producer's and a laboratory's assigned traceability system administrator to retain their account.

F. Responsibility for traceability system costs: Each producer and laboratory shall be solely responsible for all costs, including any applicable vendor fees, associated with the producer's or laboratory's use of the traceability system.

[7.35.2.16 NMAC - N, x/xx/2026]

7.35.2.17 GENERAL TRACEABILITY SYSTEM USE:

A. System required: All traceability activities of a producer and laboratory shall be tracked and reconciled daily through the use of the department-approved traceability system.

B. Weights and measures: Producers and laboratories shall utilize a standard of weights and measures that is supported by the traceability system to track all products. A scale used to weigh product prior to entry into the traceability system shall be certified to be registered and calibrated in accordance with applicable requirements of the New Mexico department of agriculture.

C. System security: Producers and laboratories shall maintain the security of the traceability system, as follows. A producer shall:

(1) maintain an accurate and complete list of all traceability system users for each permit;

(2) update the user list when a new user of the system is trained or when a previous user is removed;

(3) train and authorize any new users of the system before they are allowed to access the traceability system; and

(4) cancel the user privileges of any user and their associated accounts once the person is no longer employed by the producer.

D. Additional software allowed: Producers and laboratories may use additional software applications to collect information to be used by the business, including additional inventory tracking and point of sale systems.

E. Entry of data: Producers and laboratories shall enter data into the traceability system that fully and transparently accounts for all inventory tracking activities.

F. Use of assigned account: Individuals entering data into the traceability system shall only use that individual's traceability system account.

G. Loss of access: If at any point a producer or laboratory loses access to the traceability system for any reason, the producer or laboratory shall immediately notify the department and shall maintain comprehensive records detailing all traceability activities that occurred during the loss of access. Once access is restored, these traceability activities must be entered into the traceability system and the department notified. Producers and laboratories shall document when access to the system was lost, the cause of system loss, and when access was restored.

[7.35.2.17 NMAC - N, x/xx/2026]

7.35.2.18 COMPLIANCE NOTIFICATIONS:

A. Monitor notifications: Producers and laboratories shall monitor all compliance notifications from the traceability system or the department and shall resolve any issue(s) detailed in the compliance notification in a timely fashion. Compliance notifications from the traceability system shall not be dismissed in the traceability system until the producer resolves the compliance issues detailed in the notification.

B. Monitor informational notifications: Producers and laboratories shall take appropriate action in response to informational notifications received through the traceability system or the department including but not limited to notifications related to enforcement alerts and other pertinent information.

[7.35.2.18 NMAC - N, x/xx/2026]

7.35.2.19 REQUIRED TESTING OF PSILOCYBIN PRODUCTS: A producer shall arrange for samples to be collected and tested by an approved psilocybin testing laboratory whenever testing is required to be conducted by this rule. A producer shall ensure that testing is completed within 30 calendar days of the date of homogenization.

The homogenized lot shall pass all required tests prior to being sold or distributed for consumption.

A. Staggered implementation:

(1) The department may, within its discretion, delay or suspend implementation of sample collection, testing, and labeling requirements in whole or in part.

(2) In determining the start date of an individual testing requirement, the department shall consider whether a psilocybin testing laboratory has validated a method for conducting the test.

(3) In determining the date on which a producer must have its samples collected, the department shall consider the capacity of psilocybin testing laboratories to collect and transport samples.

B. Collection and transportation of samples; re-testing: A psilocybin testing laboratory shall collect samples from a psilocybin producer for the performance of any required test, re-test after a failed result, and re-test after remediation. A psilocybin testing laboratory may also test for the purposes of labeling.

(1) Samples shall be between 1-5 grams for every 1 kilogram of product in each homogenized lot and in accordance with the psilocybin testing laboratories sampling protocols

(2) A psilocybin testing laboratory shall develop and implement a training program for its staff concerning sample collection, transport, and testing, and shall require staff to successfully complete the training program prior to allowing staff to perform sample collection, transport of samples, or testing.

(3) The psilocybin testing laboratory may reject any sample that is suspected of having been collected in a manner that is inconsistent with the laboratory's protocol.

(4) A producer may specify reasonable precautions for a psilocybin testing laboratory to prevent the contamination of batches or lots during the sampling process; provided that the producer shall provide access to laboratory staff to the entire batch or lot to be sampled. Precautions may include, but are not limited to:

(a) requiring the use of gloves and other personal protective equipment;

(b) inspecting tools and containers prior to their use;

(c) specifying the location within the producer's establishment at which the samples will be collected;

(d) specifying locations within the producer's establishment to which laboratory staff will not have access; and

(e) the right to refuse entry to any laboratory employee or contractor not in compliance with the precautions.

C. Exception to required testing: If additional testing requirements take effect after a psilocybin testing laboratory obtains a sample for testing, the laboratory shall perform only those tests required at the time the sample was obtained.

D. Visual inspection: A sample shall be deemed to pass visual inspection tests if, under a minimum of 40x magnification, laboratory personnel detect in a one-gram sample:

(1) no living or dead insects, hair, eggs, or feces; and

(2) no more than two percent sand, soil, mold, or rocks.

E. Microbiological testing: A producer shall arrange for a sample of each homogenized lot to be collected and tested by an approved psilocybin testing laboratory for the purpose of microbiological testing, and the sample shall pass testing prior to the lot being released for sale or distribution for consumption. A producer shall arrange for additional microbiological testing of the homogenized lot and any product lot derived from the homogenized lot no less than five months and no more than six months after the lot passes a microbiological test, in accordance with the re-testing provisions of this rule. A sample shall be deemed to pass microbiological tests if the sample contains concentrations of target microbes not exceeding the action levels set forth in Table 1, *Microbiological Testing Requirements*, below.

(1) The department may require testing for additional microbes if quality control or inspection testing conducted by psilocybin testing laboratories, NMDA, or the department identifies their presence in a psilocybin product in a quantity or amount that poses a threat to public health. The department shall provide written notice to producers 30 calendar days prior to requiring additional microbiological testing, except that such notice shall not be required when human illness is linked to contaminated psilocybin products.

(2) The psilocybin testing laboratory may report a collective total of the four Aspergillus strains listed without distinguishing individual totals.

(3) The test results shall be reported as "present," "absent," or in colony forming units (CFU) per one gram sample, depending on the action level stated below.

Table 1. Microbiological Testing Requirements

Target Microbe	**Action Level**
E. coli	100 CFU/gram
Aspergillus flavus, Aspergillus fumigatus, Aspergillus niger, or Aspergillus terreus	Present
Salmonella spp.	Present
Shiga-toxin producing E. coli	Present
Clostridium botulinum	Present
Pseudomonas aeruginosa	Present
Listeria	Present
Trichoderma	Present
Total Yeast and Molds	> 20 CFU

F. Water content testing: A producer shall arrange for a sample of each homogenized lot to be collected and tested by an approved psilocybin testing laboratory for the purpose of water content testing, prior to the lot being released for sale or distribution for consumption. A producer shall arrange for additional water content testing of the homogenized lot and any product lot derived from the homogenized lot no less than five months and no more than six months after the lot is initially tested for water content, in accordance with the re-testing provisions of this rule.

G. Potency testing: A producer shall arrange for a sample of each homogenized lot to be collected and tested by an approved psilocybin testing laboratory for the purpose of potency testing, prior to the lot being released for sale or distribution for consumption. A producer shall arrange for additional potency testing of the homogenized lot and any product lot derived from the homogenized lot no less than five months and no more than six months after the lot is tested for potency, in accordance with the re-testing provisions of this rule. Potency testing shall measure the quantity of analytes identified in Table 2, "Potency Testing Requirements".

Table 2. Potency Testing Requirements		
Analyte	**CAS Number**	**Reporting Units**
Psilocybin	520-52-5	mg/gm
Psilocin	520-53-6	mg/gm
Norbaeocystin	2140-59-7	mg/gm
Baeocystin	21420-58-6	mg/gm
Aeruginascin	114264-95-8	mg/gm

H. Heavy metal testing: A producer shall arrange for a sample of each homogenized lot to be collected and tested by an approved psilocybin testing laboratory for the purpose of heavy metal testing, and the sample shall pass testing prior to the lot being released for sale or distribution for consumption. A sample shall be deemed to pass the heavy metal test if the sample contains concentrations of the analytes below the action levels stated in Table 3, *Heavy Metal Testing Requirements*.

Table 3. Heavy Metal Testing Requirements			
Analyte	**Symbol**	**CAS Number**	**Action Level**
Arsenic	As	7440-38-2	0.2 microgram/gm
Cadmium	Cd	7440-43-9	0.2 microgram/gm
Lead	Pb	7439-92-1	0.5 microgram/gm
Mercury	Hg	7439-97-6	0.1 microgram/gm
*Action levels based on USP Section 232 Elemental Impurities-Limits based on maximum of 10gm/day ingested.			

I. Pesticide testing: A producer shall arrange for a sample of each homogenized lot to be collected and tested by an approved psilocybin testing laboratory for the purpose of pesticide testing, and the sample shall pass testing prior to the lot being released for sale or distribution for consumption. A sample shall be deemed to pass the pesticide test if concentrations of targeted pesticides are lower than the action levels listed in Table 4, *Pesticide Testing Requirements*.

(1) The department may require testing for additional pesticides if quality control or inspection testing conducted by psilocybin testing laboratories, NMDA, or the department identify their presence in a psilocybin product produced or manufactured by any psilocybin establishment. The department shall provide written notice to producers 30 calendar days before implementing required testing for additional pesticide residues.

(2) Nothing in this section shall be interpreted to waive or diminish any requirement of the Pesticide Control Act, Sections 76-4-1 et seq. NMSA 1978. The department, alone or in conjunction with NMDA, may investigate any suspected use of a pesticide not registered with NMDA for use on psilocybin.

Table 4. Pesticide Testing Requirements		
Targeted Pesticide	**CAS Number**	**Action Level: ***
†Abamectin	71751-41-2	0.01
†Acequinocyl	57960-19-7	2.0
†Bifenazate	149877-41-8	0.2
†Bifenthrin	82657-04-3	0.05
†Etoxazole	153233-91-1	1.0
†Imazalil	35554-44-0	0.1
†Imidacloprid	138261-41-3	3.0

****Metrefenone**	220899-03-6	0.05
†Myclobutanil	88671-89-0	0.4
†Paclobutrazol	76738-62-0	0.04
Piperonyl butoxide	51-03-6	10
†Pyrethrins (cumulative total)	121-21-1 25402-06-6 4466-14-2	1.0
†Spinosyn A, D (cumulative total)	131929-60-7 131929-63-0	3.0
†Spiromesifen	283594-90-1	0.2
†Spirotetramat	203313-25-1	0.2
****Thiabendazole**	148-79-8	40.0
†Trifloxystrobin	141517-21-7	0.02
Other pesticide not registered with NMDA for use on psilocybin	Varies	0.02

*Micrograms of pesticide per gram (µg/g) of sample/parts per million (ppm).
Report levels less than the Limit of Quantitation for each pesticide residue according to the following example: "Paclobitrazol < 0.4 µg/g"
†Not registered with NMDA.
**Regulatory limits for mushrooms from the USDA via Foodchain application

J. Release of lot after testing: A producer may release an entire homogenized lot or product lot for sale or distribution for consumption, provided that the sample taken from the lot passes the tests required in this section.

K**. Procedures for testing:** A producer shall adhere to the following procedures:

(1) After collection of samples, a homogenized lot or product lot shall be segregated in a secure container and stored under controlled environmental conditions (temperature, humidity, light) designed to limit microbial growth or other spoilage until the producer receives a certificate of analysis indicating that the lot meets the testing requirements.

(2) The secured container shall be labeled with the identification number used in the traceability system, the name of the psilocybin testing laboratory, the date on which the samples were taken, and, in minimum 12-point font, in all capital letters, “AWAITING TEST RESULTS. DO NOT USE.”

(3) The psilocybin testing laboratory and the producer submitting samples shall both accurately and timely document the sampling and testing of the lot in the traceability system.

(4) A producer shall maintain records of all results of laboratory tests conducted for at least the preceding two years and shall make those results available to practitioners and patients upon request.

L. Re-testing:

(1) If a sample fails any test, the producer may request re-testing by the same psilocybin testing laboratory or another psilocybin testing laboratory. If the repeated test is within acceptable limits, then the lot may be released for sale or distribution for consumption.

(2) Homogenized lots and any product lots derived from a homogenized lot shall be re-tested for potency, water content, and microbiological contaminants no less than five months and no more than 6 months after the date of the previous test. Re-testing of homogenized lots and product lots shall be conducted according to the same standards as the initial test of the homogenized lot.

M. Recall and destruction: Any psilocybin lot that fails a test is subject to recall and destruction in accordance with the following:

(1) The producer shall remove the lot from inventory;

(2) If any product was previously sold or otherwise distributed from the failed lot, the producer shall notify those persons who received the product of the failed test result and shall recall the product;

(3) If any product from the failed lot has been consumed, the practitioner who dispensed the product shall forward the notification of the failed test to the qualified patient who consumed the product;

(4) The producer shall note the removal from inventory and the notice of recall in the traceability system within 24 hours; and

(5) The producer shall note the success or failure of the recall in the traceability system within seven calendar days.

[7.35.2.19 NMAC - N, x/xx/2026]

7.35.2.20 ADDITIONAL TESTING SERVICES OFFERED BY PSILOCYBIN TESTING LABORATORIES: A psilocybin testing laboratory may provide additional testing services to producers for quality improvement, research and development, or labeling purposes.

A. Research and development testing; quality control testing: A psilocybin testing laboratory may conduct such additional tests that a producer may wish to be conducted on a psilocybin product for the purposes of research and development or quality control.

(1) The producer may collect the sample, or an agent of the psilocybin testing laboratory may collect the sample.

(2) If a producer requests testing for research and development purposes, the results may not be used to satisfy any required testing requirement, even if the sample passes all tests.

(3) The failure of a test that is conducted for research and development purposes shall not constitute the failure of a test required by this rule.

(4) The results of a test conducted for research and development purposes shall not be included on a product label.

B. Testing for the purposes of labeling: A psilocybin testing laboratory may conduct such additional tests that a producer may wish to be conducted on a psilocybin product for the purposes of labeling, including but not limited to tests for additional pesticides, microbial contaminants, solvents, mycotoxins, and metals.

(1) An agent of the psilocybin testing laboratory shall collect the samples according to the laboratory's protocols.

(2) A label may include the results of the additional test.

(3) A label may include a reference to the sample passing third-party psilocybin screening criteria, including one or more of the following:

(**a**) naming the contaminants for which screening was performed;

(**b**) providing an electronic link or QR code to the list of contaminants for which the psilocybin product was screened; or

(**c**) including a statement that the product has met third-party screening criteria, such as those established by an industry association, except that no label shall contain claims that a psilocybin product is "pesticide free" or "organic" unless such statements are specifically authorized under U.S. department of agriculture regulations.

C. Reporting of contamination: Nothing in this rule shall be interpreted to require a psilocybin testing laboratory to offer testing for analytes not included in required testing. However, a psilocybin testing laboratory shall report to the department the detection of any contaminants found in these samples.

D. Testing services limited to entities in NM; tribal governments: A psilocybin testing laboratory may perform any test on a sample of psilocybin product for any entity located within New Mexico, and for any entity operated or permitted by a tribal government with which the department has an intergovernmental agreement covering psilocybin product testing. If the intergovernmental agreement permits such entities to collect and submit samples, the psilocybin testing laboratory shall provide guidance on sample collection; otherwise, an agent of the laboratory shall collect samples.

E. Testing services for the department or other governmental entities: A psilocybin testing laboratory may perform any test on behalf of the department, the NM department of agriculture, another state agency, or a state or local law enforcement authority acting within its lawful jurisdiction.

[7.35.2.20 NMAC - N, x/xx/2026]

7.35.2.21 WASTAGE OF PSILOCYBIN AND PSILOCYBIN PRODUCTS; PERMITTED METHODS:

A. A producer shall waste any psilocybin product to which a pesticide has been applied, and shall waste any product that is manufactured using an unapproved solvent.

B. Wastage of psilocybin or psilocybin products shall be accomplished by destroying, combining, or otherwise incorporating the psilocybin or psilocybin product into other material making it unusable.

C. Disposal of wasted products shall be conducted in accordance with all applicable waste disposal laws.

D. Producers shall not attempt to incorporate a wasted psilocybin product into any product intended for human consumption.

E. Producers shall record the wastage of products within 24 hours, including batch or lot number, weight, dates of wastage and disposal, and any test results associated with the wasted product, in the traceability system, and shall deduct any wasted items from inventory. The electronic record shall be retained for no less than two years following disposal.

[7.35.2.21 NMAC - N, x/xx/2026]

7.35.2.22 QUALITY ASSURANCE TESTING; COMPLAINT PROCEDURE:

A. Department-initiated quality assurance testing: The department or its representative(s) may conduct quality assurance sampling and testing of psilocybin or psilocybin products, and may require a producer to provide samples for this purpose. The department may additionally adopt and enforce a randomized testing schedule for the sampling and testing of psilocybin products, provided that a producer shall not be required to submit to randomized sampling and testing of psilocybin products more than four times within any 12-month period. The department may prohibit the sale or transfer of products that are determined by the department to contain prohibited levels of a contaminant, or that are found to have been improperly tested.

B. Testing by NMDOH scientific laboratory: The New Mexico department of health scientific laboratory may, upon the request of the program, test psilocybin and psilocybin products and may act as a reference laboratory for the program. The program may also collaborate with scientific laboratory staff for the purpose of conducting inspections of psilocybin testing laboratories and laboratory applicants.

C. Complaints: If the department receives a complaint regarding the presence of a contaminant in a psilocybin product, improper labeling of a psilocybin product, or if the department has reason to believe a contaminant or incorrect labeling may jeopardize public health and safety, the department or its representative may conduct an inspection and may require a producer to provide samples to the department for testing, which shall not be counted toward the randomized testing 12-month cap. The department shall electronically transmit any complaint to the producer, via e-mail or notification in the traceability system, within five business days of the department receiving the complaint. Producers shall allow the department or its representative(s) access to a facility or to collect samples. A complaint shall be made on a form provided by the department that at a minimum identifies:

(1) date the complaint is filed;

(2) location of the product;

(3) any identifiable features of the product at issue, including the type and amount;

(4) the nature of the complaint; and

(5) name and contact information of the complainant.

D. Department sampling and testing requirements: Department employees may possess psilocybin samples for the purposes of verifying a regulated entity's compliance with the Medical Psilocybin Act or department rules. The department shall comply with the following testing requirements:

(1) the department shall maintain chain of custody documentation for any testing samples taken;

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

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

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

(5) the quantity of psilocybin or psilocybin products that is gathered by the department from a producer for testing purposes shall not exceed the applicable testing sample sizes.

E. Costs of testing: The producer shall bear the costs of any testing required by the department.

F. Record of samples: Producers shall record in the traceability system, within 24 hours, the samples taken by the department, including batch or lot number, weight, dates the sample was taken, and any test results associated with the product, and shall deduct the samples from inventory. The electronic record shall be retained for no less than two years.

[7.35.2.22 NMAC - N, x/xx/2026]

7.35.2.23 PRODUCER REQUIREMENTS FOR SANITATION AND PRODUCT HANDLING:

Producers shall comply with the provisions of the following subparts of the 2022 United States food and drug administration model food code, which are incorporated as though fully set forth herein:

A. Subpart 1-2 (“Definitions”);
B. Subpart 2-3 (“Personal Cleanliness”);
C. Subpart 2-4 (“Hygienic Practices”);
D. Subpart 4-3 (“Numbers and Capacities”);
E. Subpart 4-4 (“Location and Installation”);
F. Subpart 4-5 (“Maintenance and Operation”);
G. Subpart 4-6 (“Cleaning of Equipment and Utensils”);
H. Subpart 4-7 (“Sanitization of Equipment and Utensils”);
I. Subpart 5-1 (“Water”);
J. Subpart 5-2 (“Plumbing System”);
K. Subpart 5-4 (“Sewage, Other Liquid Waste, and Rainwater”);
L. Subpart 6-1 (“Materials for Construction and Repair”);
M. Subpart 6-2 (“Design, Construction, and Installation”);
N. Subpart 6-3 (“Numbers and Capacities”);
O. Subpart 6-4 (“Location and Placement”); and
P. Subpart 6-5 (“Maintenance and Operation”).

[7.35.2.23 NMAC - N, x/xx/2026]

7.35.2.24 REQUIREMENTS FOR THE TRANSPORTATION OF PSILOCYBIN:

A. General requirements: Producers shall develop and maintain a plan for safe transportation of psilocybin which shall include the following requirements:

(1) transportation of psilocybin shall only be conducted by persons holding a permit or designated employees, or contractors of a permittee or certified practitioner;

(2) prior to transporting psilocybin a permittee must complete a chain of custody form, only the psilocybin listed on the chain of custody form may be transported;

(3) psilocybin shall only be transported inside of a motor vehicle in reasonable operating condition and shall not be visible or identifiable from outside of the vehicle;

(4) psilocybin shall be locked in a box, container, or cage that is secured within the inside of the vehicle, including when such a box, container, or cage is located inside of the trunk;

(5) vehicles shall be locked and secured while left unattended;

(6) vehicles shall have a vehicle alarm system;

(7) psilocybin shall not be tampered with, or opened, during transport;

(8) a person who transports psilocybin or psilocybin products may transport to multiple approved locations during one trip;

(9) a person who transports psilocybin or psilocybin products shall not deviate from the travel requirements described in this section, except for necessary rest, fuel, or vehicle repair stops;

(10) vehicles transporting psilocybin are subject to inspection by the department at any permitted premises or during transport at any time;

(11) storage and transportation of psilocybin shall be under conditions that will maintain and protect it against physical, chemical, and microbial contamination as well as against deterioration of the psilocybin and the container;

(12) the vehicle must be properly registered with the New Mexico motor vehicle division; and

(13) the driver of the vehicle must be prepared to show proper identification, including an employee badge, driver’s license, vehicle registration and proof of insurance, and the appropriate chain of custody form to law enforcement and the department when requested.

B. Chain of custody form: Prior to transporting psilocybin, a permittee shall generate and submit a chain of custody form through traceability for the following activities:

(1) testing and sampling of psilocybin;

(2) sale of psilocybin; and

(3) destruction, wastage, or disposal of psilocybin.

C. Verification of chain of custody form: The permittee receiving the psilocybin shipment will verify the psilocybin is accurately reflected in the chain of custody.

D. Rejection of shipment: Permittees shall not take into possession or transport:

(1) Any psilocybin that is not on the chain of custody form; or

(2) Any psilocybin that is less than or greater than the amount reflected on the chain of custody.

E. Responsibility for discrepancy: A permittee who transports a psilocybin product shall be responsible for any discrepancy between the chain of custody form and the psilocybin product in their possession during transport.

F. Void or change prohibited: A permittee shall not void or alter a chain of custody document after departing from the originating licensed premises.

G. Documentation of all transport: A chain of custody document shall accompany every transport of psilocybin or a psilocybin product.

[7.35.2.24 NMAC - N, x/xx/2026]

7.35.2.25 MONITORING AND CORRECTIVE ACTIONS:

A. Monitoring: The department or its designee may perform on-site assessments of a permittee or permittee-applicant, with or without prior notice, during normal business hours to determine compliance with the Medical Psilocybin Act and this rule.

B. Corrective action: If the department or its designee finds that corrective action is needed to ensure compliance with the Medical Psilocybin Act or this rule, the department shall issue notice to the permittee or permittee-applicant of the deficiency, and the permittee or permittee-applicant shall correct the deficiency within 30 calendar days.

C. Record access; interviews: The department may review any and all records related to the operation of a permittee, and may require and conduct interviews with such persons or entities, and with persons affiliated with such entities, for the purpose of determining compliance with the Medical Psilocybin Act and this rule. The department shall have access to the financial records of a permittee, including sales records, and shall be granted immediate access to inspect or copy those records upon request.

D. Referral to law enforcement: The department shall refer complaints alleging criminal activity that are made against a permittee to appropriate law enforcement authorities.

E. Financial records: A permittee shall maintain detailed sales and invoicing records in a manner and format approved by the department, and shall inform the department of the location where such records are kept, and shall promptly notify the department if the records are removed.

[7.35.2.25 NMAC - N, x/xx/2026]

7.35.2.26 DISCIPLINARY ACTIONS AND APPEAL PROCESS:

A. Immediate suspension; record review process: If immediate action is necessary to protect the health and safety of the public, the program administrator or their designee may immediately suspend the permit of a producer or laboratory in whole or in part.

(1) A permittee whose permit has been immediately suspended in whole or in part may request a record review in accordance with this part.

(2) The sole issue at a record review on a summary suspension is whether the permit shall remain suspended pending a final adjudicatory hearing and subsequent decision by the secretary.

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

(a) be made no later than 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 psilocybin program;

(c) state the requestor's name, address, and telephone number;

(d) provide a brief narrative rebutting the stated grounds for the suspension, or demonstrating that the issues which resulted in the suspension have been resolved; and

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

(4) The record review requested subsequent to an immediate suspension shall be conducted by the program administrator or their designee.

(5) The program administrator shall appoint a designee to conduct the record review by reviewing all documents submitted by the permittee and the department that are relevant to the immediate suspension.

(6) The record review shall be completed, and a written decision issued by the program administrator or their designee, no later than 15 calendar days from the date that the medical psilocybin program receives the written request for record review. The decision shall be issued to the permittee via certified U.S. postal mail.

B. Notices of disciplinary action; grounds for disciplinary action: The department may issue notice of an immediate suspension and notice of contemplated disciplinary action to a permittee. Notice shall be served upon a permittee'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.

C. Grounds for disciplinary action: Disciplinary action may be taken against a permittee or a permit-applicant. Disciplinary action may consist of revocation, or suspension in whole or in part, of a permit, denial of an application for a permit, and other actions. Disciplinary action may be imposed based on:

(a) violation of any provision of this rule;

(b) selling or distributing psilocybin or a psilocybin product in a manner that is inconsistent with rule or statute;

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

(d) intentionally destroying, damaging, altering, removing, or concealing evidence of a violation of rule or statute; attempting to do so; or asking or encouraging another person to do so;

(e) conduct that shows willful or reckless disregard for health or safety;

(f) failure to comply with the department's requested access to premises or materials;

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

(h) failure to adhere to any attestation, acknowledgement, verification, or other representation made to the department;

(i) failure to submit or disclose information required by this rule or otherwise requested by the department;

(j) failure to correct any violation of this rule that is cited as a result of a review or audit of financial records or other materials, or that is cited as a result of a monitoring visit or site inspection;

(k) a discrepancy between a chain of custody form and the transported psilocybin product;

(l) a finding of non-compliance with tax obligations by a taxation regulatory authority; and

(m) a finding by the department that any person holds an ownership interest in a permit or permittee that is nominal or without the benefits and risks of genuine ownership.

D. 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 permittee whose permit has been immediately suspended or who has received a notice of contemplated action to impose a disciplinary action; and

(2) a permit-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.

E. Timing and content of request for hearing: A permittee or permit-applicant who wishes to request a hearing may do so by mailing a written request for hearing no later than 30 calendar days from the date that the notice of contemplated action is received, or in the case of an immediate suspension, no later than 30 calendar days from the date of the immediate suspension. The request shall:

(1) be properly addressed to the medical psilocybin program;

(2) be mailed to the medical psilocybin program via certified U.S. postal mail (return receipt requested, to verify delivery);

(3) state the requestor's name, address, and telephone number; and

(4) include a statement of the issue(s) that the requestor considers relevant to the review of the action.

F. 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, provided that, if the permittee or permittee-applicant is located more than 100 miles from Santa Fe, NM, or if the parties otherwise consent, the hearing may be conducted via telephone or via web video conference;

(3) Hearings held pursuant to this section that concern patients or patient-applicants shall be closed to the public. Hearings may also be closed in whole or in part, upon the request of a party, to prevent the disclosure of information that is confidential under applicable law.

(4) The hearing shall be recorded, at a minimum, by means of sound reproduction.

G. Scheduling: The department shall schedule and hold the hearing as soon as practicable, provided that the hearing shall not be held later than 60 calendar days from the date the department receives the request for hearing. The hearing officer may 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 a notice of hearing, which shall include:

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

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

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

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

I. 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 findings or decisions recommended by the hearing officer for adoption by the secretary.

J. Recording: A party may request a copy of the recording of the proceedings.

K. 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 themselves.

(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 officer, 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, absent good cause, constitute a default.

L. Conduct of proceeding: Unless the hearing officer 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 their 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.

M. 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.

N. 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.

O. Telephonic and web video hearings:

(1) Any party requesting that a hearing be conducted via telephone or web video conference shall do so no less than 10 business days prior to the date of the hearing. Notice of the hearing shall be given to all parties and shall include all necessary telephone numbers or instructions for access to the web video conference.

(2) The in-person presence of some parties or witnesses at the hearing shall not prevent the participation of other parties or witnesses by telephone or web video conference with prior approval of the hearing officer.

P. Recommended action and final decision:

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

(2) No later than 30 calendar days after the last submission by a party, the hearing officer shall prepare and submit to the secretary a written recommendation of action to be taken by the secretary. The recommendation may include proposed findings of fact and conclusions of law for adoption by the secretary, and 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 officer's recommendation in whole or in part no later than 45 calendar days after receipt of the hearing officer'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 certified mail.

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

[7.35.2.26 NMAC - N, x/xx/2026]

7.35.2.27 SEVERABILITY: The provisions of this rule are separate and severable. If any provision of this rule is held to be invalid, unconstitutional, or unenforceable, the remaining provisions shall stay in effect.

[7.35.2.27 NMAC - N, x/xx/2026]

HISTORY OF 7.35.2 NMAC - [RESERVED]

NOTICE OF PUBLIC HEARING

The New Mexico Department of Health will hold a public hearing on the proposed adoption of a new rule, 7.35.2 NMAC, concerning the New Mexico Medical Psilocybin Program ("Program"). The hearing will be held on Friday, April 24, 2026 at 9:00 a.m. in the Harold Runnels Building auditorium, located at 1190 St. Francis Drive, Santa Fe, New Mexico. The hearing will also be broadcast via a live web-based video conference, and via telephone. Members of the public who wish to submit public comment regarding the proposed rule will be able to do so in person at the hearing, via video conference, or via telephone during the course of the hearing, and by submitting written comment.

The rule 7.35.2 NMAC proposes to adopt standards for psilocybin producers and psilocybin testing laboratories in the NM Medical Psilocybin Program. The rule includes, but is not limited to, the following:

- Section 7, "Definitions": defines various terms used in the rule;
- Section 8, "Permit Application Requirements": sets requirements for applications for producer and laboratory permits;
- Section 9, "General Permittee Requirements": sets requirements applicable to all producers and laboratories in the Program, including restrictions on transfer of permits and control and a prohibition on nominee, straw, and proxy ownership;
- Section 10, "General Producer Requirements": sets general requirements particular to producers in the Program;
- Section 11, "Allowed Psilocybin Products": prohibits adulteration of psilocybin products and requires homogenization of psilocybin products;
- Section 12, "Pesticides and Other Adulterants Prohibited": prohibits application of pesticides to fungi or growing medium;
- Section 13, "Producer Policies and Procedures": requires producers to create and maintain various policies and procedures concerning the production process and product waste;
- Section 14, "Packaging and Labeling; Product Information Document": sets standards for labeling of medical psilocybin products and creation of an associated product information document;
- Section 15, "General Tracking Requirements": requires tracking of batches and lots, and wasting of psilocybin material, using the Department's identified traceability system;
- Section 16, "Implementation and Administration of Traceability System": requires designation of users of the Department-identified traceability system, training of users, and continuing education;
- Section 17, "General Traceability System Use": requires maintaining an accurate user list, and cancellation of user accounts for users who are no longer employed by the producer;
- Section 18, "Compliance Notifications": requires that producers and laboratories monitor compliance notifications and informational notifications in the traceability system;
- Section 19, "Required Testing of Psilocybin Products": sets standards for laboratory testing of psilocybin products for microbiological contaminants, water content, potency, heavy metals, and pesticides.
- Section 20, "Additional Testing Services Offered by Psilocybin Testing Laboratories": authorizes additional psilocybin testing for purposes of quality improvement, research and development, and labeling;
- Section 21, "Wastage of Psilocybin and Psilocybin Products; Permitted Methods": requires that any psilocybin product to which a pesticide has been applied be converted to waste;
- Section 22, "Quality Assurance Testing; Complaint Procedure": authorizes QA testing by the Department of Health, and describes how complaints can be submitted;
- Section 23, "Producer Requirements for Sanitation and Product Handling": incorporates various provisions of the 2022 FDA Model Food Code;
- Section 24, "Requirements for the Transportation of Psilocybin": sets requirements for transport of psilocybin products;
- Section 25, "Monitoring and Corrective Actions": authorizes the Department to perform on-site assessments of a permittee or permit applicant, interview persons affiliated with permittees; and
- Section 26, "Disciplinary Actions and Appeals Process": establishes procedures for disciplinary actions against permit holders and applicants for a permit, including grounds for disciplinary actions, and the process for requested administrative hearings.

The purpose of the proposed rule 7.35.2 NMAC is to implement the Medical Psilocybin Act, sections 26-2D-1 through -11, NMSA 1978.

The legal authority authorizing the adoption of this rule by the Department is the Department of Health Act, subsection E of section 9-7-6 NMSA 1978, which authorizes the secretary of the department of health to "...make and adopt such reasonable and procedural rules and regulations as may be necessary to carry out the duties of the department and its divisions,"; and the Medical Psilocybin Act, at section 26-2D-7, NMSA 1978, which requires the Department to promulgate requirements, restrictions, and limitations for the Program, as well as necessary training, safety protocols, best practices, and requirements for data collection.

A free copy of the full text of the proposed rule can be obtained online from the New Mexico Department of Health's website at http://nmhealth.org/about/asd/cmo/rules/ or by contacting the Department using the contact information below.

The public hearing will be conducted to receive public comment on the proposed rule. Any interested member of the public may attend the hearing and may submit data, views, or arguments on the proposed rule either orally or in writing during the hearing.

The hearing will be held on April 24, 2026 at the Harold Runnels Building auditorium, located at 1190 St. Francis Drive, Santa Fe, New Mexico.

To access the hearing via the Internet: please go to https://www.microsoft.com/en-us/microsoft-teams/join-a-meeting and then enter the following meeting i.d. code and passcode where indicated on the screen: meeting i.d. code 228 537 544 934 10 and passcode tL3eH7yM and then click the "Join a meeting" button.
To access the hearing by telephone: please call 1-505-312-4308 and enter phone conference i.d. 467 689 840#

All comments will be recorded.

Written public comment regarding the proposed rule can be submitted either by e-mail to Jacob Clark at jacob.clark@doh.nm.gov, or by U.S. postal mail to the following address:

Jacob Clark
NMDOH OGC
P.O. Box 26110
1190 St. Francis Dr., Suite N-4095
Santa Fe, NM 87502-6110

Written comments must be received by the close of the public rule hearing on April 24, 2026. All written comments will be published on the agency website at https://www.nmhealth.org/about/asd/cmo/rules/ within 3 days of receipt, and will be available at the New Mexico Department of Health for public inspection.

If you are an individual with a disability and need special assistance or accommodation to attend or participate in the hearing, please contact Jacob Clark by telephone at (505) 827-2997. The Department requests at least ten (10) days' advance notice to provide special accommodation.

EXHIBIT 4

Affidavit of Publication

STATE OF NEW MEXICO } SS
COUNTY OF BERNALILLO }

Ad Cost:	$328.68
Ad Number:	374620
Account Number:	1060434
Classification:	GOVERNMENT LEGALS

I, Michele Aster, the undersigned, Legal Representative of the Albuquerque Journal, on oath, state that this newspaper is duly qualified to publish legal notices or advertisements within the meaning of Section 3, chapter 167, Session Laws of 1937, and payment of fees has been made of assessed and a copy of which is hereto attached, was published in said publication in the daily edition, 1 time on the following date:

March 24, 2026

That said newspaper was regularly issued and circulated on those dates.
SIGNED:

Legal Representative

Subscribed to and sworn to me this 24th day of March 2026.

Notary Public

_____ County Bernalillo
ID#: 1140229
My commission expires: 04-26-2027

STATE OF NEW MEXICO
NOTARY PUBLIC
DAVID LINDSEY MONTOYA
COMMISSION NUMBER 1140229
EXPIRATION DATE 04-26-2027

NM DEPT OF HEALTH
OFFICE OF GENERAL COUNSEL
PO BOX 26110, SUITE N-4095
SANTA FE, NM 87502

NOTICE OF PUBLIC HEARING

The New Mexico Department of Health will hold a public hearing on the proposed adoption of a new rule, 7.35.2 NMAC, concerning the New Mexico Medical Psilocybin Program ("Program"). The hearing will be held on Friday, April 24, 2026 at 9:00 a.m. in the Harold Runnels Building auditorium, located at 1190 St. Francis Drive, Santa Fe, New Mexico. The hearing will also be broadcast via a live web-based video conference, and via telephone. Members of the public who wish to submit public comment regarding the proposed rule will be able to do so in person at the hearing, via video conference, or via telephone during the course of the hearing, and by submitting written comment.

The rule 7.35.2 NMAC proposes to adopt standards for psilocybin producers and psilocybin testing laboratories in the NM Medical Psilocybin Program. The rule includes, but is not limited to, the following:

- Section 7, "Definitions": defines various terms used in the rule;
- Section 8, "Permit Application Requirements": sets requirements for applications for producer and laboratory permits;
- Section 9, "General Permittee Requirements": sets requirements applicable to all producers and laboratories in the Program, including restrictions on transfer of permits and control and a prohibition on nominee, straw, and proxy ownership;
- Section 10, "General Producer Requirements": sets general requirements particular to producers in the Program;
- Section 11, "Allowed Psilocybin Products": prohibits adulteration of psilocybin products and requires homogenization of psilocybin products;
- Section 12, "Pesticides and Other Adulterants Prohibited": prohibits application of pesticides to fungi or growing medium;
- Section 13, "Producer Policies and Procedures": requires producers to create and maintain various policies and procedures concerning the production process and product waste;
- Section 14, "Packaging and Labeling; Product Information Document": sets standards for labeling of medical psilocybin products and creation of an associated product information document;
- Section 15, "General Tracking Requirements": requires tracking of batches and lots, and wasting of psilocybin material, using the Department's identified traceability system;
- Section 16, "Implementation and Administration of Traceability System": requires designation of users of the Department-identified traceability system, training of users, and continuing education;
- Section 17, "General Traceability System Use": requires maintaining an accurate user list, and cancellation of user accounts for users who are no longer employed by the producer;
- Section 18, "Compliance Notifications": requires that producers and laboratories monitor compliance notifications and informational notifications in the traceability system;
- Section 19, "Required Testing of Psilocybin Products": sets standards for laboratory testing of psilocybin products for microbiological contaminants, water content, potency, heavy metals, and pesticides.
- Section 20, "Additional Testing Services Offered by Psilocybin Testing Laboratories": authorizes additional psilocybin testing for purposes of quality improvement, research and development, and labeling;
- Section 21, "Wastage of Psilocybin and Psilocybin Products; Permitted Methods": requires that any psilocybin product to which a pesticide has been applied be converted to waste;
- Section 22, "Quality Assurance Testing; Complaint Procedure": authorizes QA testing by the Department of Health, and describes how complaints can be submitted;
- Section 23, "Producer Requirements for Sanitation and Product Handling": incorporates various provisions of the 2022 FDA Model Food Code;
- Section 24, "Requirements for the Transportation of Psilocybin": sets requirements for transport of psilocybin products;
- Section 25, "Monitoring and Corrective Actions": authorizes the Department to perform on-site assessments of a permittee or permit applicant, interview persons affiliated with permittees; and
- Section 26, "Disciplinary Actions and Appeals Process": establishes procedures for disciplinary actions against permit holders and applicants for a permit, including grounds for disciplinary actions, and the process for requested administrative hearings.

The purpose of the proposed rule 7.35.2 NMAC is to implement the Medical Psilocybin Act, sections 26-2D-1 through -11, NMSA 1978.

The legal authority authorizing the adoption of this rule by the Department is the Department of Health Act, subsection E of section 9-7-6 NMSA 1978, which authorizes the secretary of the department of health to "...make and adopt such reasonable and procedural rules and regulations as may be necessary to carry out the duties of the department and its divisions,"; and the Medical Psilocybin Act, at section 26-2D-7, NMSA 1978, which requires the Department to promulgate requirements, restrictions, and limitations for the Program, as well as necessary training, safety protocols, best practices, and requirements for data collection.

A free copy of the full text of the proposed rule can be obtained online from the New Mexico Department of Health's website at http://nmhealth.org/about/asd/cmo/rules/ or by contacting the Department using the contact information below.

The public hearing will be conducted to receive public comment on the proposed rule. Any interested member of the public may attend the hearing and may submit data, views, or arguments on the proposed rule either orally or in writing during the hearing.

The hearing will be held on April 24, 2026 at the Harold Runnels Building auditorium, located at 1190 St. Francis Drive, Santa Fe, New Mexico.

To access the hearing via the Internet: please go to https://www.microsoft.com/en-us/microsoft-teams/join-a-meeting and then enter the following meeting i.d. code and passcode where indicated on the screen: meeting i.d. code 228 537 544 934 10 and passcode tL3eH7yM and then click the "Join a meeting" button.
To access the hearing by telephone: please call 1-505-312-4308 and enter phone conference i.d. 467 689 840#

All comments will be recorded.

Written public comment regarding the proposed rule can be submitted either by e-mail to Jacob Clark at jacob.clark@doh.nm.gov, or by U.S. postal mail to the following address:

Jacob Clark
NMDOH OGC
P.O. Box 26110
1190 St. Francis Dr., Suite N-4095
Santa Fe, NM 87502-6110

Written comments must be received by the close of the public rule hearing on April 24, 2026. All written comments will be published on the agency website at https://www.nmhealth.org/about/asd/cmo/rules/ within 3 days of receipt, and will be available at the New Mexico Department of Health for public inspection.

If you are an individual with a disability and need special assistance or accommodation to attend or participate in the hearing, please contact Jacob Clark by telephone at (505) 827-2997. The Department requests at least ten (10) days' advance notice to provide special accommodation.

Journal: March 24, 2026.

EXHIBIT 5

INVOICE

NM Commission of Public Records
1205 Camino Carlos Rey
Santa Fe, NM 87507

darlene.martinez@srca.nm.gov
+1 (505) 476-7912
www.nmcpr.state.nm.us

Bill to
Department of Health - General Counsel
Office
P.O. Box 26110
Santa Fe, NM 87502-6110

Ship to
Department of Health - General Counsel
Office
P.O. Box 26110
Santa Fe, NM 87502-6110

Invoice details
Invoice no.: SRCA 8734
Terms: Due on receipt
Invoice date: 03/26/2026
Due date: 03/26/2026

Volume: XXXVII
Issue: 6
P.O. number: 66500-0000205339

#	Product or service	Description	Qty	Rate	Amount
1.	**NM Register - 431902**	Notice Of Public Hearing (7.4.3 NMAC), hearing date: 4/30/2026	26	$3.00	$78.00
2.	**NM Register - 431902**	Notice Of Public Hearing (7.30.12 NMAC), hearing date: 5/15/2026	30	$3.00	$90.00
3.	**NM Register - 431902**	Notice Of Public Hearing (7.35.2 NMAC), hearing date: 4/24/2026	37	$3.00	$111.00

Total **$279.00**

Note to customer

Thank you for your business!

NEW MEXICO
State Records Center and Archives
COMMISSION OF PUBLIC RECORDS
Your Access to Public Information

Affidavit of Publication in New Mexico Register

I, Matthew Ortiz, certify that the agency noted on Invoice # SRCA - 8734 has published legal notice of rulemaking or rules in the NEW MEXICO REGISTER, VOLUME XXXVI, that payment has been assessed for said legal notice of rulemaking or rules, which appears on the publication date and in the issue number noted on Invoice # SRCA - 8734, and that Invoice # SRCA - 8734 has been sent electronically to the person(s) listed on the *Billing Information Sheet* provided by the agency.

Affiant: _____
Matthew Ortiz

Subscribed, sworn and acknowledged before me this 27th day of March 2026.

Notary Public: _____
My Commission Expires: 1/22/2028

PAMELA ANNE LUJAN Y VIGIL
Notary Public
State of New Mexico
Comm. # 2001927
My Comm. Exp. Jan 22, 2028

EXHIBIT 6

Via Electronic Mail

March 5, 2026

Craig Erickson
Utton & Kery, P.A.
PO Box 2386
Santa Fe, NM 87504
E-mail: craig@uttonkery.com

Re: Appointment Letter, Public Rulemaking Hearing on Proposed Adoption of a New Rule 7.35.2 NMAC, the New Mexico Psilocybin Program

Dear Mr. Erickson:

Pursuant to NMSA 1978, § 9-7-6(E), I hereby appoint you to serve as the hearing officer to preside at the Department of Health's public hearing April 24th, 2026, and to submit a written recommendation regarding the proposed rule adoption. This rulemaking hearing is scheduled for 9:00 a.m. and will be a hybrid rule hearing, conducted in-person at the Harold Runnels Building auditorium, located at 1190 St. Francis Drive, Santa Fe, New Mexico 87505, and via the Microsoft Teams web conference platform and via telephone. Attached is a copy of the Notice of Public Hearing.

The hearing will be conducted to receive public comment regarding the adoption of a new rule, 7.35.2 NMAC, "New Mexico Psilocybin Program". An exhibit binder will be provided to you prior to the date of the hearing.

Thank you for accepting this appointment.

Sincerely,

Gina DeBlassie
NMDOH Cabinet Secretary

3/5/2026
Date

cc: Christopher D. Woodward, Deputy General Counsel

Affidavit of Notice to the Public

I, Jacob Clark, the undersigned, on oath, swear and affirm that the Notice of the Public Hearing for the proposed adoption of rule 7.35.2 (New Mexico Medical Psilocybin Program), was provided to the public as identified below:

1. On March 24th, 2026, I verified that the Notice of Public Hearing was electronically posted on the New Mexico Department of Health agency website at https://www.nmhealth.org/about/asd/cmo/rules/, in accordance with the State Rules Act at NMSA 1978, § 14-4-5.2.

2. On March 24th, 2026, I verified that the Notice of Public Hearing was posted on the New Mexico Sunshine Portal website, in accordance with the State Rules Act at NMSA 1978, § 14-4-5.2.

3. On March 24th, 2026, I emailed the Notice of Public Hearing to persons who have made a written request for notice from the agency of announcements addressing the subject of rulemakings and who have provided the agency an electronic mail address, in accordance with the State Rules Act at NMSA 1978, § 14-4-5.2. The list of persons who requested notice includes the following persons:

Tim Gardner	tgardner@drnm.org
Lucy Galaviz	lgalaviz@drnm.org
Rachel S. Gudgel	rachel.gudgel@nmlegis.gov

4. No persons have provided a postal address to request written notice by postal mail.

5. On March 24th, 2026, I emailed the Notice of Public hearing to the New Mexico Legislative Council Service, at lcs@nmlegis.gov, in accordance with the State Rules Act at NMSA 1978, § 14-4-5.2.

6. On March 24th, 2026, I emailed the Notice of Public Hearing to Kim Sewell of the New Mexico Small Business Regulatory Advisory Commission, the identified contact person for the receipt of proposed rule changes, at Kim.Sewell@edd.nm.gov, pursuant to the Small Business Regulatory Relief Act at NMSA 1978, § 14-4A-4.

7. On March 24th, 2026, I ensured that the Notice of Public Hearing was posted publicly on the exterior doors at the Harold Runnels Building, Department of Health, 1190 S. St. Francis Drive, Santa Fe, NM 87505.

FURTHER AFFIANT SAYETH NAUGHT.

Jacob Clark, Affiant

STATE OF NEW MEXICO }
COUNTY OF SANTA FE }

SWORN TO and SUBSCRIBED before me on the 25 day of March, 2026 by Jacob Clark.

Notarial Officer

My Commission Expires:

NA Bar # 14653

State of New Mexico
Notarial Officer
Amanda H. Frazier
State Bar #14653

LIST OF ANTICIPATED REVISIONS TO 7.35.2 NMAC

This is a list of revisions that the Department anticipates making to the proposed rule 7.35.2 NMAC. This list includes edits that the Department plans to make at this point. However, it is not a final list, and the Department will continue considering the written and oral public comments.

1. 7.35.2.7(A)(1) NMAC; revise definition of "actual control" as follows:

(1) **"Actual control"** means the ability to:

(a) [~~direct~~] control the policies, management, [~~and~~] or personnel of a permittee;

(b) [~~exert authority over~~] control strategic priorities, capital allocations, acquisitions, and divestments of a permittee; or

(c) control a majority of voting rights of a permittee.

These revisions are proposed to ensure that persons who assume an ownership interest in a permittee, including investors, can exert authority over the permittee's business, while still preventing a transfer of majority control (i.e., the ability to totally control the business) to any one person. For example, by removing the "exert authority" text and replacing it with the word "control", the rule would allow a person who purchases an ownership interest in a permittee to vote their shares.

This revision is also intended to ensure that the definition of "actual control" does not conflict with the "genuine ownership" requirements at 7.35.2.9(B) NMAC, which effectively require that persons who hold an ownership interest in a permittee be able to exert authority over the permittee as one of the "customary incidents of ownership".

2. 7.35.2.7(A)(2) NMAC; revise definition of "administration session" as follows:

(2) **"Administration session"** means the [~~therapeutic session combined with the administration of~~] session in which psilocybin is administered.

This revision is proposed to narrow the definition of "administration session", to more clearly delineate between administration sessions that involve the actual administration of psilocybin, and therapy sessions that do not involve psilocybin administration.

3. 7.35.2.7(I)(2) NMAC; revise definition of "inoculate" as follows:

(2) **"Inoculate"** means the process of introducing psilocybin spores [~~of~~] or mycelium into growth medium.

The definition accidentally included the word "of" instead of "or", and is corrected here.

4. 7.35.2.8 NMAC; revise application submittal requirements concerning rental properties as follows:

A. **General requirements:** An applicant for a producer or laboratory permit shall provide to the department and shall maintain the following records: * * * *

(9) proof of ownership of the facility or [~~written approval from the owner to cultivate psilocybin on the premises~~] a signed, written statement from the owner of the property acknowledging that the owner understands that psilocybin products will be produced or tested on the premises;

This revision is meant to substitute a written acknowledgement from the property owner for the previously proposed "approval" from the owner.

5. 7.35.2.9(C) NMAC; revise restriction on transferability of permits as follows:

C. Permits non-transferable: A permit shall not be transferred by sale, assignment, or otherwise, except as approved by the department upon the death of a sole proprietor.

This revision is meant to create an exception to the general prohibition against the transfer of permits, in the limited circumstance where a permittee is a sole proprietor, and the sole proprietor dies. In those circumstances involving sole proprietors, the only way the entity could continue in operation is if the permit is transferred in its entirety. This text would allow that transfer, provided that the Department approves it.

6. 7.35.2.19(E) NMAC, Table 1; revise "Total Yeast and Molds" Action Level from > 20 CFU to > 1,000 CFU.

This revision is based on the recommended limit set by the American Herbal Products Association (AHPA) for yeasts and molds in powdered dried food products.

7. 7.35.2.19(F) NMAC; specify that "Water content shall be less than 10%" in order to pass water content testing.

This revision proposes to set a cap on the maximum water content that a psilocybin product can contain before it can be released for sale or distribution for consumption. The Department believes that a 10% cap on water content is reasonable and will suffice to reduce bacterial growth.

8. 7.35.2.26(B) NMAC; specify that a courtesy copy of a notice of immediate suspension or notice of proposed disciplinary action will be transmitted to the permittee via e-mail, in addition to service via certified U.S. postal mail.

This was meant to be included in the proposed rule, but was accidentally omitted. These notices will still be issued by certified U.S. mail, but they'll also go out via e-mail to the e-mail address of record for the permittee.

9. 7.35.2.19 NMAC, Table 4; modify certain pesticide testing action levels, as follows:

†Abamectin	71751-41-2	[~~0.01~~] 0.15
†Bifenthrin	82657-04-3	[~~0.05~~] 0.1
**** [~~Metrefenone~~] Metrafenone**	220899-03-6	[~~0.05~~] 0.5

These are revised to correct typographical errors and to more closely reflect relevant standards used for cannabis testing.

EXHIBIT 9

From: Brown, James
To: Clark, Jacob, DOH; Brown, James
Subject: [EXTERNAL] Additional Comments on Definitions for Submission on the Producer and Laboratory Requirements
Date: Tuesday, April 14, 2026 4:37:45 PM
Attachments: 9605.pdf

Jacob,

I wanted to submit the following comments on the Definitions for the Producer and Lab Requirements. My comments are in Red.

Thank You,
James Brown

Referring Clinician - Definition: A licensed clinician acting within their scope of practice who possesses diagnostic authority. Please include examples of who this would be ie: Physicians, CNP, PA, Psychiatrist, other Specialized Clinicians – Pharmacist & Other Specialist. The participant has been provided medical clearance by the participant's referring clinician.

- The Referring Clinician must document and maintain reasonable evidence of a consultation and risk review taking place, and if the consultation and risk review identifies heightened risk associated with a specific condition, the participant must work with the referring clinician to develop a safety plan, informed by the consultation and risk review, and provide written informed consent to work with the Cliniican.

Determining Clinician - Definition: A clinician operating within their authorized scope, responsible for determining medical appropriateness for psilocybin treatment. Please include examples of who this would be ie: Physicians, CNP, PA, Psychiatrist, other Specialized Clinicians – Pharmacist & Other Specialist.

- The Determining Clinician must document and maintain reasonable evidence of a consultation and risk review taking place, and if the consultation and risk review identifies heightened risk associated with a specific condition, the participant must work with the Determining Clinician to develop a safety plan, informed by the consultation and risk review, and provide written informed consent to work with the Clinician.

Guides or Facilitators - Definition: A licensed or certified individual trained in psilocybin facilitation and therapeutic support. Please include examples of who this would be ie:

Physicians, CNP, PA, Psychiatrist, Licensed Social Works, Caplins, Death Dulas, Natural Medicine Doctor, Pharmacist, Nursing, & Other Healthcare Professionals.

- The Guide/Facilitator must document and maintain reasonable evidence of a consultation and risk review taking place, and if the consultation and risk review identifies heightened risk associated with a specific condition, the participant must work with the Facilitator to develop a safety plan, informed by the consultation and risk review, and provide written informed consent to work with the Facilitator.

Integration Provider - Definition: A clinician or trained professional providing post-session therapeutic integration. Please include examples of who this would be ie: Focus would be on Therapist, Licensed Social Workers, Physicians, CNP, PA, Psychiatrist, Psychologist, other Specialized Clinicians – Pharmacist & Other Specialist and Healthcare Professionals.

From: Brown, James <jbrown9@phs.org>
Sent: Tuesday, April 14, 2026 4:33 PM
To: jacob.clark@doh.nm.gov <jacob.clark@doh.nm.gov>; Brown, James <jbrown9@phs.org>
Subject: Fw: Comments for Submission on the Producer and Laboratory Requirements

To: Jacob Clark

Here are my comments for submission and addition to the following section (in Red) :

Thank You,
James Brown

M. Recall and Destruction:

PURPOSE:

To define a method by which psilocybin & psilocin recalls for substances discontinued for safety reasons will be handled.

RECALL DEFINITIONS:

• Class 1 recall: a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequence or death.

• Class 2 recall: a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

• Class 3 recall: a situation in which use of or exposure to violative product is not likely to cause adverse health consequences.

STATEMENT OF POLICY:

• All psilocybin and psilocin involved in a recall notice will be handled per New Mexico Department of Health regulations.

• Recall notices are available from many sources which may include wholesalers, manufactures, the N.M. Department of Health. Each will be treated as a potential harmful until proven otherwise.

• Once a notice is received, the facility personnel with inspect all the products and floor stock for the specific product recalled.

• If any psilocybin or psilocin is found on the recall notice, anywhere within the facility, it will be immediately removed from circulation and quarantined.

• The facility has a quarantine area for recalled and expired psilocybin and psilocin within the facility. The container is labelled “OUTDATED/RECALLED/DO NOT USE” wording.

• At this time the class of the recall will determine what course of action needs to be taken.

• All class 2 and 3 recalls will be processed as per recall instructions.

• For a class 1 recalls, patients must be notified of the recall, it may be done by registered mail, phone, or whatever it takes.

• Facility system sale records will be reviewed back as far as necessary to protect patient safety. (I.e.; Facility Name; address; contact info)

• Copies of recalls notices received by the facility will be kept within the facility whether we had the product or not. The recall paperwork will be signed and dated as to whether we had the product or not.

• All recall notices will be filed within the facility, these records will be available for inspection for 5 years.

• All recall notices will be reported to the Safety Committee at the next scheduled meeting and scanned into the DOH electronic system.

• Incident reports will be done on any patient receiving class 1 recall psilocybin or psilocin prior to recall.

• When psilocybin or psilocin are recalled or discontinued for safety reasons prescribers and those who dispense or administer the medication will be notified.

7.35.2.9 General Permittee Requirements:

B. Dual Ownership prohibited: A person who holds an ownership interest in a permittee shall not hold an interest in any other permittee. – A person who holds an ownership interest in a producer or laboratory permittee shall not hold an interest in another producer or laboratory permittee. A person holding either a producer or laboratory permittee is allowed to hold an interest in other permittee excluding interest in another producer or laboratory permittee.

I believe this restriction is unnecessarily limiting and may hinder the development of safe, efficient, and patient-centered care models in New Mexico. Allowing a single entity to operate both a cultivation facility and a treatment facility—provided they are clearly separated—would improve continuity of care, product consistency, and operational efficiency.

I recommend that the Board allow dual licensure under the following conditions:

- Each operation must be located in **separate suites with distinct addresses and entrances**
- There must be **no shared or common walls** between the cultivation and treatment areas
- Each facility must undergo **independent licensing, inspections, and regulatory compliance processes**
- Clear physical and operational separation must be maintained to ensure safety, security, and regulatory integrity

This approach maintains strict oversight while enabling responsible operators to provide a more integrated and reliable patient experience. It also supports the development of a stable supply chain and reduces barriers that could otherwise limit access to treatment.

By allowing dual licensure with proper safeguards, New Mexico can foster innovation while maintaining the highest standards of safety and compliance.

Joint Public Comment: NMAC 7.35.2 Proposed Propagation Regulations

By: Healing Advocacy Fund and Rudick Law Group
Authors: Denali Wilson, Esq. and Victoria J. Cvitanovic, Esq.

Introduction

Healing Advocacy Fund and Rudick Law Group respectfully submit the following comments to the Department of Health's proposed regulations governing New Mexico's Medical Psilocybin Program (the "Program"). In our review of the draft rules, we focused on compliance implementation, financial feasibility, and liability reduction for all parties involved. Addressing these areas thoroughly will dramatically impact equity and access within the program.

Commentary Framework and Perspective Applied

New Mexico's Program is genuinely novel. As the first state to implement a fully medically-integrated psilocybin program, the regulatory decisions made now will shape the Program's safety, integrity, accessibility, investability, and equity for years to come. We approach this comment from a place of commitment to the Program's success and a sincere commitment to accomplishing the goals of the Department.

In preparing these comments, we applied a deliberately critical lens, asking how opposing counsel, investors, financiers, and others could use the current draft regulations to undermine the Department's goals of protecting New Mexican operators, patients, and providers to further their own interests. We believe that this perspective allows the Department to best anticipate risk and make strategic decisions. The issues we identify are solvable, and we are committed to working collaboratively with the Department toward solutions.

Concerns Addressed

Our comments address four primary areas of concern:

1. Gaps in protections against predatory financing and disguised control;
2. Clarity regarding rules into investment into permitted businesses;
3. The feasibility, costs, and risks of compliance posed by the draft rules,
4. Other equity and access issues; and
5. Issues the proposed regulations create related to insurance coverage for care and professional liability insurance[1]

For each concern identified, we offer a recommended solution. We welcome direct conversation on any of these topics and are available to discuss our analysis and recommendations at the Department's convenience.

[1] Much of the identified issues related to insurance (both professional liability and care coverage) arise from the definitions section of the draft rules. We understand that those regulations will not be finalized until their corresponding regulations are promulgated. We offer the feedback now in order to better prepare for those forthcoming rule promulgations.

The issues identified in this comment are serious. If left unaddressed, they present meaningful risks to safety, stability of supply chain, accessibility, and participation in the regulated Program, risks that would undermine the very goals the Medical Psilocybin Act was designed to achieve. However, **New Mexico is more than capable of navigating these risks.** The Department is the ideal evaluator of risk prioritization, analysis, and strategic reduction.

The Department has many options for addressing these issues. We offer a perspective guided by our experience in building and undoing transactions, addressing risks created by regulatory gaps, drafting and negotiating leases, representing license holders and investors, working with government, and litigating against government. It is with confidence that the risks identified can be mitigated that we offer this comment.

1) Gaps in protections against predatory financing and disguised control.

Summary of Problem

Predatory financing in this context can be defined as follows:

- Predatory financing, in the context of licensed psilocybin cultivation, is any financing arrangement in which the **economic terms**, **structural features**, or **contractual conditions**, whether individually or in combination, effectively transfer **operational control**, **primary economic benefit**, or **decision-making authority** over a licensed cultivator to an unlicensed third party, without that party undergoing the licensing and suitability review required of a direct owner or controlling party.

- Predatory financing is distinct from legitimate investment risk, which includes market-rate interest, standard loan covenants protecting collateral, equity stakes with proportionate governance rights held by vetted investors, and revenue-sharing arrangements tied to actual profit rather than gross extraction. The rules should not be so broad that they discourage the capital formation that participants in the Program need.

Two primary harms result from predatory financing:

1. **Economic extraction,** and
2. **Disguised Control.**

Economic extraction should be thought of as arrangements designed to strip revenue or assets from the permittee on terms no commercially reasonable lender or investor would demand absent leverage over a regulated entity. Businesses participating in state programs that allow otherwise federally illegal conduct are particularly vulnerable to economic extraction risks, as these businesses are often excluded from traditional financing and the dignified banking market.

Disguised control refers to arrangements that don't look like ownership on paper but functionally give the financing party the ability to direct cultivation practices, hiring, vendor selection, or exit decisions. This is often achieved through covenant packages, exclusive supply or service agreements bundled with the financing, board observer rights, or consent rights over material business decisions.

These two harms frequently appear together and reinforce each other. A predatory lender gains leverage through punishing economic terms, then uses that leverage to exercise de facto control. Neither of these issues are disclosed to regulators because the party never appears as a licensed owner. The financing arrangement becomes the mechanism for regulatory evasion.

When regulators address predatory financing, a single question can guide those efforts: **Would the proposed financing arrangement, taken as a whole, give the financing party influence over the licensee that would require licensure if that influence were exercised through direct ownership?** If so, that arrangement should require permittee-level disclosures and responsibilities that flow to the financier, or it should be prohibited.

Risk Analysis–Predatory Financing and Disguised Control

Operators in the psychedelic industry face capital access barriers that are unlike those in most regulated industries. Because psilocybin remains a Schedule I substance under federal law, most banks and conventional lending institutions will not provide financing to businesses operating in this space. This creates conditions in which small operators — often those most aligned with the equity and healing principles at the heart of the Medical Psilocybin Act — are dependent on private capital arrangements that carry significant risk of exploitation. Comparable dynamics in the cannabis industry have contributed to widespread hardship, forced bankruptcies, and the erosion of equity goals in state-regulated programs across the country.

The draft regulations, as written, attempt to address these risks by broadly restricting ownership arrangements and transfers of control. However, the current approach is overbroad in ways that would unintentionally prohibit beneficial arrangements, like friends-and-family investment and legitimate minority ownership stakes, and potentially destabilize the supply chain in ways that create profound risk for Program participants, such as facing a permit transfer ban after the death of a permittee.

We believe the solution is not to restrict investment broadly, but to distinguish clearly between those who exercise actual control over a permitted business and those who hold a passive financial interest. The suggested amendments below offer a framework for protecting permittees and the program from bad-faith actors while preserving access to the limited capital available in this field.

The following section provides suggested amendments to address these concerns, along with explanations interspersed throughout.

The first few suggested amendments address defining “actual control” in a clear, enforceable manner that permittees can use to assess their compliance, defining “true party in interest” to ease identification of actual control, and defining “minority participant,” to define people and entities who have a meaningful connection to a permittee but who do not have actual control over, or responsibility for, the actions of a permittee.

Original Definition:

“Actual control” means the ability to:
(a) direct the policies, management, and personnel of a permittee;
(b) exert authority over strategic priorities, capital allocations, acquisitions, and divestments of a permittee; or
(c) control a majority of voting rights of a permittee.

Suggested Amendment:

7.35.2.7(A)(1) **“Actual control”** means the direct or indirect authority, influence, or power, whether exercised or merely held, and whether formal or informal, written or unwritten, by which a natural person or entity directs or is capable of directing the management, policies, operations, or financial affairs of a permittee.

"Actual control" includes control exercised through any intermediary person or entity. A person or entity exercises "Actual Control" if that person or entity:

(a) Holds an ownership interest of 20% or more in a permittee, whether directly or indirectly through one or more intermediary entities, trusts, or persons;
(b) Holds the position of manager, managing member, general partner, trustee, or any functionally equivalent role with governing authority over the permittee, regardless of the organizational form of the permittee;
(c) Holds a seat on the board of directors or governing body of a permittee, or holds board observer rights that include the ability to speak, present information, or otherwise participate in board deliberations;
(d) Has authority, as evidenced by the permittee's formation documents, operating agreements, bylaws, financing agreements, management services agreements, side letters, or actual practices, whether written or oral, to direct the policies, management, or personnel of the permittee, including the ability to hire or terminate employees, officers, or contractors, or to enter into binding agreements on behalf of the permittee. The existence of such authority, whether or not exercised, is sufficient to establish actual control under this prong;
(e) Has authority, alone or in combination with others, to make decisions regarding the strategic priorities, capital allocations, acquisitions, divestments, key vendor or supply relationships, product pricing or supply agreements, or regulatory compliance matters of a permittee;

(f) Controls 20% or more of the voting rights of a permittee, or otherwise holds voting rights sufficient to constitute effective control given the permittee's ownership and governance structure; or
(g) Otherwise exercises, or holds the capacity to exercise, dominant influence over the management, policies, financial affairs, or operations of the permittee, regardless of formal title, equity stake, or documented authority.

(A)(2) **Aggregated influence considered.** In determining whether a person or entity exercises actual control, the Department shall consider the totality of the person or entity's relationship with the permittee, including the combined effect of ownership interests, contractual rights, financing arrangements, and any other formal or informal authority. No single prong need be satisfied to establish actual control if the person or entity's aggregate relationship with the permittee is consistent with the exercise of dominant influence as described in prong (7).

Why consider an amendment?

The revised definition moves away from the original's focus on "the ability to" take certain actions (which is difficult to prove and easy to disclaim) toward a definition grounded in formal authority as established by ownership records, formation documents, and actual business practices. This makes the definition more administrable for the Department and harder to evade through creative structuring.

Original Definition:

7.35.2.7(G)(1) "Genuine ownership" means an ownership interest in an applicant or a permittee that is evidenced by record ownership in which the owner, regardless of the amount of capital or assets that the owner contributes to the applicant or permittee, enjoys the customary incidents of ownership and shares in the profits and losses of the permittee proportionate to the percentage of the owner's interest in the permit.

Suggested Amendments:

At 7.35.2.7(G)(1), it is suggested that the Department **strike** the "Genuine Ownership" definition. Instead, it is suggested that the Department define a "True Party in Interest" and a "Minority Participant" and associated regulations for reach.

(INSERT APPROPRIATE CITATION) "True Party in Interest" ("TPI") means any person or entity who exercises Actual Control over a permittee as defined herein, regardless of whether that person holds a formal ownership interest, officer title, or other documented role with the permittee. A true party in interest need not be a named owner, officer, or employee of the permittee to qualify as such under this definition.

(INSERT APPROPRIATE CITATION) Presumed TPI. The Department may presume that a person or entity is a TPI upon a finding of any of the following: the person or entity has directly or indirectly provided financing to the permittee on terms that include operational covenants,

consent rights, or control triggers; the person or entity holds a management services, consulting, or similar agreement with the permittee; the person or entity has regularly acted as a representative of the permittee in dealings with regulators, suppliers, or customers; or the person or entity has received compensation or economic benefit from the permittee disproportionate to any disclosed role or investment. This presumption may be rebutted by clear and convincing evidence.

(INSERT APPROPRIATE CITATION) TPI Disclosures. Every person or entity who qualifies as a TPI with respect to a permittee must be identified by name on all permit applications, renewal applications, and material change notifications submitted to the Department. Failure to disclose a TPI shall constitute grounds for denial, suspension, or revocation of a permit, and may constitute a separate violation subject to civil penalty.

(INSERT APPROPRIATE CITATION) Continuing Obligation. A permittee has a continuing obligation to disclose any new or changed TPI within 30 days of the change. A change in a TPI that has not been disclosed to and approved by the Department shall constitute an unauthorized transfer of Actual Control and grounds for permit revocation.

(INSERT APPROPRIATE CITATION) Equivalent Scrutiny. Each TPI must submit to all investigation, disclosure, and compliance obligations as a named permit applicant.

(INSERT APPROPRIATE CITATION) Equivalent Compliance. Each TPI is jointly and severally responsible with the permittee for the permittee's compliance with all applicable statutes, rules, and permit conditions. Regulatory action, including suspension, revocation, civil penalty, or corrective order, may be taken against any TPI on the same basis as against the permittee. A TPI may not avoid compliance responsibility by delegating operational duties, withdrawing from day-to-day management, or asserting that Actual Control was not exercised during the period of the violation. The capacity to exercise Actual Control during the relevant period is sufficient to establish responsibility under this prong.

(INSERT APPROPRIATE CITATION) Failure to Disclose Not a Defense. A TPI who is found to have exercised Actual Control over a permittee without having been disclosed to the Department shall be subject to the same penalties as the permittee for any violations occurring during the period of undisclosed control, in addition to any independent penalties for failure to disclose.

(INSERT APPROPRIATE CITATION) “Minority Participant” means any person or entity who contributes capital, labor, services, intellectual property, or other value to a permittee, or who participates in the operations of a permittee in any compensated or ownership-bearing capacity, but who does not exercise Actual Control over the permittee and is not a TPI. A Minority Participant has a cognizable relationship with the permittee but does not bear the compliance responsibilities of a TPI solely by virtue of minority participant status. A person or entity qualifies as a Minority Participant if they fulfill any of the categories and do not exercise Actual Control:

(a) Minority capital investor. A person or entity who holds a direct or indirect ownership interest of less than 20% in the permittee, or who holds a debt instrument, revenue participation right, or other financial interest in the permittee, where that interest does not carry governance rights, operational covenants, or other features that would satisfy the Actual Control definition;

(b) Sweat equity contributor. A person or entity who has received or is entitled to receive an ownership interest, profit participation, or deferred compensation in exchange for services rendered to the permittee, where that interest or entitlement does not, at the time of vesting or receipt, cause the person or entity to satisfy any prong of the actual control definition;

(c) Key employee or officer. A person employed by or engaged as an officer of the permittee in a role that involves regular access to controlled substances, cultivation operations, financial records, or regulatory compliance functions, or who exercises significant operational responsibility within a defined function, but whose authority does not extend to Actual Control;

(d) Operational participant. A person who regularly participates in the day-to-day cultivation, processing, handling, storage, or transfer of psilocybin products on behalf of the permittee, including supervisory personnel whose authority is limited to a defined operational function or site;

(e) Contracted service provider with operational access. A person or entity engaged by the permittee under a services, consulting, or management agreement who, by virtue of that engagement, has regular physical access to cultivation premises, psilocybin products, or the permittee's financial or compliance systems, but whose contractual authority does not independently constitute Actual Control; or

(f) Contingent interest holder. A person or entity who holds an option, warrant, convertible instrument, or other contingent right to acquire an ownership or economic interest in the permittee, where exercise of that right would result in the person qualifying as a Minority Participant.

Why consider an amendment?

As written, the definition and use throughout of “genuine ownership” is vague and may invite litigation. It is also unclear how a party can contribute to a permittee if they wish to minimize their own risk, limiting the pool of investment available to permittees, even from friends and family who may wish to assist without acquiring responsibility for controlled substance cultivation. By defining two distinct categories of participation, the Department can regulate actual control, avoid disguised control, prevent predatory financing, and encourage investment.

Note: The Department may well require registration and disclosures from Minority Participants, even though they aren't TPIs. The suggested definition contemplates the addition of Minority Participant responsibilities, even if those responsibilities do not rise to the level of that which is expected from a TPI.

2) Clarity regarding rules into investment into permitted businesses

Summary of Problem

Under the current draft regulations, it is unclear whether and how a party could invest in a permittee without taking responsibility for the compliance and actions of that permittee. Given the lack of traditional investment vehicles available in the space, such ambiguity could lock needed capital, like friends and family investments, out of local operations.

Suggested Amendments re Investment

Original Text:

7.35.2.1 GENERAL PERMITTEE REQUIREMENTS:

A. Compliance with applicable laws: A permittee shall comply with all applicable state, tribal, and local laws, regulations, and ordinances, including requirements concerning agriculture, environmental health, building and occupancy, fire safety, zoning, and worker safety.
B. Dual ownership prohibited: A person who holds an ownership interest in a permittee shall not hold an ownership interest in any other permittee.
C. Permits non-transferable: A permit shall not be transferred by sale, assignment, or otherwise. A permit that is transferred shall be invalid.
D. Transfer of actual control prohibited: An applicant or permittee shall not transfer actual control of the applicant or permittee to any person using a management, consulting, or intellectual property agreement, or by any other means. A transfer of actual control shall invalidate an associated permit.
E. Nominee, straw, and proxy ownership prohibited: A person shall not apply for or hold a permit if any ownership interest in the permit is nominal or without the benefits and risks of genuine ownership or control.
F. Record of financial interests: Permittees shall create and maintain complete lists of all individuals and legal entities that hold a financial interest in the permittee or the operations of the permittee, including contact information for each individual or entity and a description of their financial interest. Applicants and permittees shall provide the information required by this section to the department within 15 calendar days of the department's written request for such information. If a legal entity holds a financial interest in the permittee or the permittee's operations within the medical psilocybin program, the following individuals within the legal entity shall be deemed to also hold a financial interest:
(1) For limited partnerships, each general partner in the limited partnership;
(2) For limited liability companies, each manager and managing member of the limited liability company;
(3) For for-profit corporations, each principal officer of the corporation; and
(4) For non-profit entities, each principal officer of the entity. [7.35.2.9 NMAC - N, x/xx/2026]

Suggested Amendment:

7.35.2.2 GENERAL PERMITTEE REQUIREMENTS:

A. Compliance with applicable laws. A permittee shall comply with all applicable federal, state, tribal, and local laws, regulations, and ordinances, including requirements concerning agriculture, environmental health, building and occupancy, fire safety, zoning, and worker safety. Each TPI shall bear responsibility for the permittee's compliance therewith.

B. Dual Participation Prohibited. A TPI with respect to a permittee shall not hold an ownership interest in, exercise actual control over, or qualify as a TPI with respect to any other permittee. For purposes of this section, ownership or participation held indirectly through an intermediary entity, trust, or nominee shall be treated as direct ownership or participation.[2]

C. Transfer of Permit Prohibited. A permit may not be transferred by sale, assignment, operation of law, or any other means without approval by the Department. Any purported transfer of a permit without Department approval shall render the permit invalid. For purposes of this section, a change in the TPI(s) of a permittee, including a change resulting from a transfer of ownership interest, a change in actual control, or a restructuring of the permittee's legal form, constitutes a transfer of the permit and requires prior Department approval.

D. Transfer of Actual Control Prohibited. An applicant or permittee shall not transfer Actual Control of the applicant or permittee to any person or entity who has not been disclosed to and approved by the Department as a TPI. Actual control shall not be transferred through a management, consulting, intellectual property, financing, or services agreement, or by any other means, formal or informal, written or oral. A transfer of Actual Control that has not been approved by the Department shall invalidate the associated permit and may constitute a separate violation subject to civil penalty. For purposes of this section, "transfer of Actual Control" includes any arrangement by which a person or entity acquires the capacity to exercise Actual Control as defined herein, regardless of whether Actual Control has been exercised.

E. Exception, Succession. As part of an application for a permit under these regulations, and as a continuous obligation for maintaining such permit, a permitee is required to maintain a succession plan approved by the Department that provides for the transfer of a TPI's interest and Actual Control in the event of the death or dissolution of each TPI. A transfer under a Department-approved succession plan is not prohibited by these regulations.

F. Disguised Control Prohibited. No person or entity shall, directly or indirectly, exercise, acquire, or maintain Actual Control over a permittee through any arrangement, device, or scheme designed to conceal that control from the Department or to avoid the disclosure, suitability, and compliance obligations applicable to a TPI. The substance of a person's or entity's relationship with a permittee governs; formal title, documented role, and the nominal terms of any agreement are not determinative. A finding that Actual Control over a permittee is

---

[2] **Note: Some examples of regulations include a waiver provision like the following:**

The Department may grant a waiver upon written application demonstrating that the dual participation does not create a risk of supply concentration, regulatory evasion, or conflict of interest inconsistent with the Program's public health objectives.

Authors recognize that waiver is an issue that is deeply personal to how states want to spend their resources, and leave that issue to the Department.

or has been disguised in violation of this section shall constitute grounds for permit denial, suspension, or revocation. The Department shall designate the person or entity found to be exercising disguised control as a TPI, subject to all obligations and liabilities attendant to that status, including compliance responsibility for violations occurring during the period of disguised control. Entering into or maintaining an arrangement prohibited by this section is a separate violation that may be subject to civil penalty, regardless of whether any other violation of the permittee's obligations has occurred. Disguised control includes, without limitation, any of the following arrangements where the purpose or effect is to enable a person or entity to exercise Actual Control without disclosure:

1. Holding an ownership, economic, or governance interest in a permittee through a nominee, straw party, proxy, or intermediary entity whose identity is disclosed in place of the person exercising actual control;
2. Entering into a financing, loan, or debt instrument that includes operational covenants, consent rights, default triggers, or other terms that give the financing party the capacity to direct the management, policies, or operations of the permittee, whether or not that capacity has been exercised;
3. Entering into a management, consulting, services, intellectual property, supply, or licensing agreement that grants the counterparty authority over the permittee's operations, personnel, compliance functions, or strategic decisions to a degree that would constitute actual control if held by a disclosed owner or officer;
4. Executing side agreements, oral understandings, or undisclosed amendments that alter the governance rights, economic terms, or operational authority established in documents filed with or disclosed to the Department;
5. Distributing ownership interests, voting rights, or governance authority across two or more persons and/or entities acting in concert in a manner designed to ensure that no single person or entity's disclosed interest appears to satisfy Actual Control, while collectively those persons and/or entities exercise Actual Control; or
6. Holding a contingent right, including an option, warrant, convertible instrument, or debt acceleration clause, that, upon exercise or trigger, would transfer Actual Control to an undisclosed or unapproved person or entity.

Nothing in this section prohibits a permittee from entering into commercially reasonable financing, service, or operational agreements on arm's-length terms that do not confer Actual Control to the counterparty.

G. Record of financial interests. A permittee shall create and maintain a complete, current, and accurate record of all persons and legal entities that hold a present financial interest and/or convertible interest in the permittee. The record shall include, for each such person or entity: full legal name and contact information; the nature, form, and approximate value of the financial interest; whether the person or entity is a TPI or Minority Participant; and a description of whether the financial interest is present or subject to any contingent rights to acquire or expand a financial interest, including options, warrants, and convertible instruments. The permittee shall provide the information required by this section to the Department within 15 calendar days of a written request. The record shall be updated within 30 days of any material change.

Where a legal entity holds a financial interest in a permittee or the permittee's operations, the following persons within that entity are deemed to also hold a financial interest and must be individually disclosed:

1. For limited partnerships: each general partner;
2. For limited liability companies: each manager and managing member;
3. For for-profit corporations: each principal officer;
4. For non-profit entities: each principal officer; and
5. For trusts: each trustee and, where the trust is revocable, each settlor. Where a trust holds an interest of 20% or more, each beneficiary with a vested interest in the trust must also be disclosed.

The look-through obligation imposed by this section applies at each level of a multi-tier ownership structure. Where an entity that holds a financial interest in the permittee is itself owned or controlled by one or more additional entities, the Department may require disclosure of the persons exercising actual control at each tier until the natural persons who are the ultimate beneficial owners and controllers of the permittee have been identified.

Why consider an amendment?

By tying the dual ownership prohibition to TPI status rather than any ownership interest, the amendment allows passive minority investment across multiple permittees while still preventing any single person from controlling more than one permitted business. This directly addresses the concern about sophisticated investors using investments in multiple operations as a vehicle for consolidating influence over the industry while preserving the ability of legitimate investors to support multiple permittees.

The original provision broadly prohibited any transfer of actual control through management, consulting, or intellectual property agreements. While the intent was sound, the provision created compliance uncertainty for legitimate arrangements, such as shared services agreements between related entities. Likewise, the lack of a succession provision created significant liability concerns for spouses, children, and others who may be left with possession of Schedule I substance cultivation facilities and no legal permit in the case of a TPI’s death.

The revised framework addresses the underlying undue influence concerns while protecting legitimate investors, friends and family, and business partners. No person should worry that if their spouse or business partner dies, or if an entity dissolves through no fault of their own, that they are suddenly and irrevocably in possession of Schedule I cultivation facilities with no legal protection.

The disguised control provision does the core work of the predatory financing protections. It prohibits any arrangement (regardless of its form) through which a person who is not a TPI exercises actual control over a permittee. By framing the prohibition around function rather than form, the amendment closes the drafting gaps that sophisticated actors would otherwise exploit. The suggested amendment also expressly allows minority investment while making clear that investment cannot be a vehicle for back-channel control.

3) Overall Compliance Feasibility and Clarity

Summary of Problem:

The draft regulations establish requirements for product traceability, food safety, and contaminant testing that are essential to patient safety in the regulated access program, and we support their inclusion. However, in certain sections the draft regulations may exceed what patient safety requires, and in others they fail to provide operators with a clear, administrable compliance standard. Both problems carry real costs. Overly burdensome or redundant testing requirements will drive up production costs of medical psilocybin that will ultimately be passed on to patients, or absorbed by the state and deplete the Treatment Equity Fund. And where compliance standards are vague, operators cannot reliably meet them, creating enforcement uncertainty and legal exposure for good-faith participants in the program.

Recommended Action:

On cost feasibility: We recommend that the Department conduct and publish a cost analysis of the testing and production requirements as currently drafted before the regulations are finalized. It is likely that some requirements will need to be recalibrated as the program matures. We therefore also recommend that the Department build implementation review metrics into the program from the outset — tracking testing costs and contaminant presence data over time with an explicit eye toward long-term feasibility — so that the regulatory framework can be adjusted based on evidence rather than crisis.

On compliance clarity: Where the draft regulations set compliance standards that are ambiguous or undefined, operators are left to guess at what conduct will satisfy the requirement. This creates inequitable enforcement — operators with more resources can obtain legal guidance; those without cannot — and exposes good-faith operators to disciplinary action for conduct that reasonable actors could interpret as compliant. We recommend that the Department review the draft regulations for undefined compliance standards and either specify the required conduct directly in the regulatory text or commit to publishing compliance guidance alongside the final regulations.

The following amendment illustrates the problem and our recommended approach:

Original Text:

7.35.2.1(B) Wastage of psilocybin or psilocybin products shall be accomplished by destroying, combining, or otherwise incorporating the psilocybin or psilocybin product into other material making it unusable.

Suggested Amendment:

7.35.2.1(B) Wastage of psilocybin or psilocybin products shall be accomplished by destroying *(by heat treatment, freeze treatment, or other means rendering the substance biologically inactive)*, combining, or otherwise incorporating the psilocybin or psilocybin product into other material making it unusable.

Why consider an amendment?

Where the original draft regulations prescribe wastage by "destroying" the product, it does not prescribe what means of destruction are permitted, leaving cultivators to guess what process of destruction is permitted. Consultation with Oregon and Colorado state program operators suggest that heat or freeze treatment is a viable, cost conscious means of product wastage.

Original Text

7.35.2.10(A) GENERAL PRODUCER REQUIREMENTS:

A. A producer shall [...]

Suggested Amendment

7.35.2.1 GENERAL PRODUCER REQUIREMENTS:

[insert preceding section]

A. A "producer" is:

(1) An LLC, Corporation, or Nonprofit Corporation properly authorized to do business in the State of New Mexico,

(2) Who has been granted the appropriate license under the Medical Psilocybin Program to cultivate psilocybin

(3) Who is engaged in the cultivation of psilocybin on the premises permitted by such license, and

(4) Who meets all of the requirements for maintaining such license.

A producer may hold a license under New Mexico's cannabis regulations (INSERT CITE) that authorizes cannabis-related activities at the same location as the producer's psilocybin production location, provided that the producer:

(1) Owns the land on which the production of cannabis and psilocybin takes place, or (INSERT REVISED LANDLORD ATTESTATION LANGUAGE, ADDRESSED BELOW).

If a producer who holds a license under New Mexico's cannabis regulations (INSERT CITE) and under the Medical Psilocybin Program has one of those licenses properly revoked under New Mexico law, the other license shall be automatically revoked.

Why consider an amendment?

The draft regulations at 7.35.2.10(A) set out what a producer is required to do, but do not explicitly define who is eligible to become a producer. This gap creates compliance uncertainty at the threshold of program participation. Operators cannot reliably assess their eligibility before investing in an application, and the Department lacks a clear regulatory basis for consistent eligibility determinations.

A related ambiguity concerns dual licensure. The draft regulations do not address whether a cultivator currently licensed under New Mexico's cannabis program may also hold a producer license under the Medical Psilocybin Program. This silence is likely to create unnecessary

barriers for a class of operators who are among the best positioned to participate in the psilocybin program: cannabis cultivators already have compliance infrastructure, existing relationships with state regulators, and demonstrated capacity to operate in a Schedule I-adjacent regulated environment.

4) Other Equity and Access Issues

Summary of Problem:

The draft regulation at 7.35.2.8(A)(9) requires applicants to provide "proof of ownership of a facility, or written approval from the owner to cultivate psilocybin on the premise." While we understand the Department's interest in ensuring that operators have secure, stable access to their cultivation sites, the written approval requirement as drafted creates significant practical barriers and unintended risks.

Landlords, even those who are supportive of their tenants and of the Program, are unlikely to provide written approval to engage in conduct that remains federally illegal on their premises. **Such an attestation would amount to written proof in a legally binding document of aiding and abetting the manufacture of a Schedule I substance**, exposing even the most well-intentioned and supportive landlord to civil and criminal liability. The requirement also creates an opening for exploitation. Landlords who understand that a written approval is a regulatory prerequisite may use that leverage to extract unfair terms or higher rent from tenants seeking to operate in the program.

Original Text:

7.35.2.8A(9)...proof of ownership of the facility, or written approval from the owner to cultivate psilocybin on the premises;

Suggested Amendment:

7.35.2.8A(9)...proof of ownership of a facility, a lease agreement that adequately protects the right of the program licensee to participate in the Medical Psilocybin Program, or written approval from the owner to participate in the Program. Such lease or approval may be contingent upon the permittee’s continued compliance with Program requirements.

Why consider an amendment?

The suggested amendment addresses these concerns by replacing the written approval requirement with three alternatives that provide equivalent regulatory assurance **without requiring landlords to attest to aiding and abetting federally illegal activity**. Under the amended language, an applicant could satisfy the requirement by providing either proof of ownership, a lease agreement that adequately protects the applicant's right to participate in the Medical Psilocybin Program, or an attestation allowing for Program participation rather than requiring a landlord to attest that the permitee may cultivate psilocybin on the property regardless of Program participation. Think of the situation where a permit is revoked. Under the

current language, a permitee could pivot a landlord's premises into illegal production relying on the same attestation the Program required to prevent eviction.

Under this amendment, where a landlord's written approval is still sought, the amendment narrows the scope of that approval to participation in a licensed Department of Health program, reducing the landlord's legal exposure while preserving the Department's ability to verify site access. Likewise, the lease agreement pathway reflects established practice in industries that operate legally under state law but remain subject to federal prohibition. In those industries, it is standard for tenants and landlords to negotiate an "anti-illegality waiver," which is a specialized contract provision through which the landlord voluntarily waives the right to void the lease on the basis of the tenant's state-legal but federally prohibited activities. This waiver protects both parties by giving the operator regulatory certainty and lease security, while giving the landlord a negotiated, clear path to eviction if the leasee fails to comply with the state program both parties rely on to reduce their liability. To support implementation, the Department could publish a model lease clause on its website establishing a baseline standard (i.e. "this level of protection or higher") that landlords and tenants could adapt to their circumstances. Standardizing this requirement across all license categories in the Medical Psilocybin Program, and considering parallel adoption in the cannabis regulatory framework, would create consistency across New Mexico's state-legal but federally prohibited industries and reduce compliance uncertainty for operators and property owners alike. **We are happy to provide model clauses if desired.**

5) Issues the Proposed Regulations Create Related to Insurance Coverage for Care

Summary of Problem:

As New Mexico's medically-integrated psilocybin program is the first of its kind in the country, it must address a regulatory challenge that has no established roadmap: how to structure a care model that preserves insurance coverage for the services patients are already entitled to receive. The Department is, in effect, helping to define a new insurance market. How the Program's components are described in regulation will directly determine what arguments third party payors will use as grounds to deny coverage. Where ambiguity exists, insurers will exploit it, and the resulting costs will fall on patients and providers.

As detailed in the previously submitted memo, *Medicaid Coverage and the Medical Psilocybin Act: Meeting Pre-existing Obligations and Avoiding Discrimination*, the core insurance problem for patients is this: most Medicaid and third-party payer contracts contain provisions that prohibit coverage for services provided in connection with an "unapproved treatment modality." For Psychedelic Assisted Therapy (PAT), the unapproved treatment modality is the **actual administration or self-administration** of a Schedule I substance. This prohibition is not new, and it is not unique to psilocybin; it is a standard feature of third-party payor contracts that reflects longstanding refusal to pay for non-FDA approved treatments. **This prohibition means that any service the regulations define as part of the administration of a Schedule I substance will likely not be paid for by any insurance, government or private.**

Currently, the draft regulations refer to both the actual administration or self-administration of psilocybin and the other (usually covered) medical care that happens as the patient experiences the effects of psilocybin as the "administration session." **Coverage planning becomes difficult, if not impossible, when unapproved and normally covered components of care are combined in regulatory language.** The medical care constituting preparation and integration services (the testing, medication monitoring, medical monitoring, crisis intervention, and behavioral health services that precede and follow administration) are behavioral health services that Medicaid and third-party payers cover in virtually every other clinical context. They should remain coverable here. **However, because draft regulations describe these services in ways that tie them to the administration of psilocybin, they create a basis for insurers to treat the entire continuum of care as part of an unapproved treatment modality, and to decline coverage accordingly.**

This risk is not hypothetical, but rather, the predictable consequence of regulatory language that fails to maintain a clear separation between the components of care that involve a Schedule I substance and those that do not. The solution is not to minimize or obscure the role of psilocybin in the program. The solution is to ensure that the regulatory definitions describing preparation and integration services can stand independently of the administration, so that coverage for those services is not contingent on the resolution of questions about a Schedule I substance. The suggested amendments below are aimed at addressing these issues.

A second, more downstream risk is also perpetrated by the current draft regulations. As the first medically-integrated state psilocybin program in the country, New Mexico faces professional liability questions that have no precedent and no established insurance framework to resolve them. These questions are made more urgent (and more complex) by the fact that New Mexico's Medical Malpractice Act was substantially amended during the 2026 legislative session, after the Medical Psilocybin Act was adopted in 2025. The regulations must now be read against a liability landscape that has shifted since the underlying statute was written.

The Program is dependent on clinician participation. The fewer clinicians are willing to take the risk of participation, a risk that implicates their clinical licensure, prescriber licensure, and long-term insurability, the less accessible Program care will be. By tying “administration” to the other care a clinician might provide, the regulations increase the chance that a participating clinician may be disciplined, lose licensure, or have their insurance coverage dropped. State programs cannot forget that they do not control or influence every licensing authority or insurance company a clinician is subject to. Clinicians may be licensed in multiple states, hold DEA prescriber authority, or depend on non-local insurers for professional liability protection. A clear separation between Schedule I administration and other care is required to protect the clinicians who, by accepting risk for patient wellbeing, will build this Program.

The specific problem is this: where regulation or statute describes the administration of a Schedule I substance as the provision of "medical services," that characterization risks bringing such activities within the scope of the Medical Malpractice Act. This creates a serious coverage gap. Medical malpractice insurance covers claims arising from the provision of medical services, but insurers underwriting those policies did not price, and will not cover, claims arising

specifically from the administration of a substance that remains federally illegal to possess, manufacture, sell, or distribute. Providers could therefore find themselves subject to Medical Malpractice liability obligations for activities that their malpractice insurance will not cover, leaving them personally exposed in the event of a claim.

We recognize that some of the professional liability issues identified in the draft regulations come from the language of the MPA itself. Full resolution of those issues may require statutory amendment, and Rudick Law Group is preparing a forthcoming memo on medical malpractice liability under the MPA that will include any such legislative recommendations. However, addressing these issues proactively in the draft regulations (to the extent the statute permits) will provide meaningful clarity for providers now and avoid the need to revise the regulations to conform with future statutory changes that are, in our view, likely necessary.

Suggested Amendments re Insurance Coverage

Original Definition:

7.35.2.7.A(2) “Administration session” means the therapeutic session combined with the administration of psilocybin.

Suggested Amendment:

Strike “Administration session.” Instead, define “Program,” “Program Participant,” “Administration,” and “Other Care.”

~~7.35.2.7.A(2) “Administration session” means the therapeutic session combined with the administration of psilocybin.~~

(INSERT APPROPRIATE CITATION) "Program" means the New Mexico Medical Psilocybin Program established under the Medical Psilocybin Act.

(INSERT APPROPRIATE CITATION) “Program Participant” means a patient who receives care authorized by the Program from Authorized Providers permitted to administer Program services at the time the patient receives care.

(INSERT APPROPRIATE CITATION) "Administration" means the act of a Program Participant ingesting psilocybin within a context authorized by the Program, exclusive of any Other Care provided before, during, or after that ingestion.

(INSERT APPROPRIATE CITATION) "Other care" means all therapeutic, clinical, preparatory, and integrative services provided to a Program Participant within the Program other than Administration, including patient assessment, informed consent, preparation sessions, presence and observation during a treatment session, and integration support following administration.

Why consider an amendment?

By combining therapy with the administration of psilocybin in this draft definition, we invite Medicaid and other third party payors to decline coverage for behavioral health care they would cover in any other circumstance, creating affordability and access barriers that harm the long-term viability of the state program. These recommended revisions reframe the program components in ways that protect the patient's best chance at accessible care and protect clinicians from avoidable risk.

If these changes are adopted, the definition of "Guide" will also need to change. Currently, the definition of "Guide" invites allegations of the unauthorized practice of medicine, further undermining a clinician who works with Guide's ability to maintain licensing and insurance while participating in the Program. Moreover, if Guides are providing assisting in the provision of clinical care, there is potential for attempts at tying medical malpractice liability to Guide services.

Original Definition:

7.35.2.7.G(3) "Guide" an individual who completed training and education approved by the department to be able to assist practitioners during the administration session and who has been registered with the department.

Suggested Amendment:

7.35.2.7.G(3) "Guide" means an individual who has completed Department-approved training and education and has been registered with the Department, and whose role is limited to providing non-clinical support and presence to a patient preparing for, experiencing the effects of, or integrating the effects of Administration, as allowed by the Program. A Guide does not perform, and shall not be construed to perform, clinical assessment, diagnosis, treatment, or any other act constituting the practice of medicine, nursing, or any other licensed health profession. A Guide does not act under the supervision, direction, or authority of any licensed health care provider, and no provider shall be deemed to have supervisory responsibility over a Guide solely by virtue of their concurrent participation in any part of the Program.

Why Consider an Amendment?

The core problem with the current definition is that "assist practitioners during the administration session" implies a subordinate clinical relationship that could cut both ways, either exposing guides to malpractice liability for clinical acts they are not licensed to perform, or creating a supervisory relationship that makes the practitioner responsible for the guide's conduct in ways neither party intends. There is no reason that a Guide should worry about medical malpractice suits, or that a Clinician should worry that working with a Guide could undermine their professional security. Guides are not providing clinical services, and the regulations should make that clear.

Original Definition:

7.35.2.7.M(2) “Medical services” means services provided to a patient in an approved setting before, during and after the ingestion of psilocybin and includes a preparation session, an administration session, and an integration session.”

Suggested Amendment

7.35.2.7.M(2) **"Medical services"** means the clinical and therapeutic services provided to a patient by a licensed practitioner within the Program, including patient assessment, diagnosis, testing, medication management, behavioral health services, crisis health services, and the like. Medical services does not include Administration, nor does it include the non-clinical support provided by a Guide. The provision of Medical Services by a practitioner during or proximate to the services provided by a Guide does not automatically create a supervisory relationship between that practitioner and any Guide.

Why consider an amendment?

The definition as it is has two problems. First, it collapses administration and other care into a single undifferentiated concept. Second, the phrase "medical services" implies a clinical character for all Program services, including Administration. We understand that this definition comes directly from the MPA. However, as explained above, by defining services provided surrounding the ingestion of psilocybin as medical services, the definition creates potential insurance, supervisory, malpractice, and other concerns which will likely reduce clinician participation in the Program. That decline in accessibility can be prevented.

Conclusion

New Mexico faces opportunity and struggle as it commits to serving patients through the Medical Psilocybin Program. The suggestions contained herein attempt to ease New Mexico’s future struggles by identifying risk and ways to reduce it. Thank you for your consideration and continued work. We hope to act as a resource to support that work as rulemaking continues.

Rule 7.35.2 NMAC Public Comment concerning the Medical Psilocybin Program – Propagation Regulations

From: John Starr, Strong Medicine.
JStarr@strongmedicine.com
(505) 933-1166

Date: 23 April 2026

Submitted electronically to jacob.clark@doh.nm.gov

Comments:

The success of any program resulting from legislation lies in the rule making. There has been broad and diverse participation on behalf of healing practices and, ethical and equity concerns, while the practical business concerns had less participation. This is not a criticism, but simply an observation by a businessman, who could not always participate himself. The committees have been well organized, staffed well and the discussions have been at a high level. The passion for this treatment was obvious from the outset.

My concerns have been and continue to be with the ability to justify investment with the proposed limitations. It appears that the majority of those interested in the psilocybin growing business in NM are small businesses. The rule making should be in favor of supporting small business. It is well documented that most small businesses fail due to lack of working capital (Investment). The proposed rules approach is limiting to encouraging investment to the extent that significant failures are likely, thus restricting access to the product for medical purposes, and sets the stage to having the price of the medicine out of reach for many of the patients who need it most.

The recent announcement by the Federal Government to reconsider the Schedule 1 drug list has added an element of uncertainty that the “investment world” is pushing the pause button on any future investment plans. All these uncertainties beg the question, “What safeguards prevent this program from becoming either too expensive for patients or too unprofitable for local producers?”

The committee recently provided several documents from committee participants addressing the proposed rules. One of these documents, co-authored by Danali Wilson, Esq. and Victoria J Cvitanovic, Esq., recognized many of my concerns specifically as to ownership and investment. Their approach anticipates typical short comings in rule making, i.e., ambiguities and conflicts in definitions, and over regulation. Their document summarized many of my concerns with the rules, and stated, ***“The rules should not be so broad that they discourage the capital that participants in the Program need.”***

I am a businessman, not a medical provider, nor attorney, nor drafter of rules. I do know the risks of starting and owning a business. I hope, in the spirit of equity, being a "businessman" is not seen as a bad thing. We need individuals to take risks. We need individuals to financially invest in this program. I hope that these rules can be shaped in a manner to provide the protections we all support, without overly restricting the capital it takes to make this a successful program.

This is our first and most important concern. I believe many of the other shortcomings of the law will work themselves out during implementation. The issues I mention above speak to the actual potential success of the program and the individuals and companies that are interested in taking on the work and investment to bring this important medicine to those who need it.

I have never taken part in any type of rulemaking. It has been a learning experience, and I thank you for the opportunity to provide these comments.

PSYCHEDELIC BAR ASSOCIATION
SEE • INTEGRATE • ADVOCATE • ADVISE

Psychedelic Bar Association
P.O. Box 12
Leadville, CO 80461
Tel: (303) 915-0658)
www.ThePsychedelicBar.org

April 24, 2026

New Mexico Department of Health
Medical Psilocybin Program
PO Box 26110
Santa Fe, NM, 87502-6110
jacob.clark@doh.nm.gov

VIA EMAIL

RE: *Comment on Draft Rule 7.35.2 NMAC*

To the New Mexico Department of Health:

The Psychedelic Bar Association (PBA) is a 501(c)(3) nonprofit association of lawyers and legal professionals committed to the creation of a world where safe, legal, access to psychedelics brings healing, equity and justice for all. We, the New Mexico Working Group of the PBA, formed in early 2026 to offer issue-area expertise during the development of the state-regulated program in New Mexico. We are eager to support the success of the New Mexico state regulated access program and are grateful for the opportunity to provide feedback on Rule 7.35.2 NMAC. Our feedback covers the following areas:

1. Principles of Regulation
2. Intersections of Medical and Religious Use
3. Federal Tax Consequences
4. Anticipating and Reducing Negative Consequences of Profit Motives
5. Restrictors for Property-Renting Applicants

1. Principles of Regulation

With the right set and setting, the psilocybin experience consistently ranks among the top 5 most personally meaningful and spiritually significant experiences of a person's entire life—comparable in importance to the death of a parent or birth of a

child.[1] We believe it is of paramount significance that New Mexico's groundbreaking Medical Psilocybin Program be affordable and accessible to everyone who could benefit. Failure to create an affordable and accessible system will deprive low- and middle-income communities of the astonishing health and life outcomes that psilocybin frequently occasions.

The key considerations for a regulatory framework that is designed to affordable and equitable access include:

1. The safeguards must be proportionate to the safety concerns. If the safety requirements are higher than necessary, it will raise the costs to the detriment of low- and middle-income communities. Many of the most important safety concerns can be inexpensively resolved through screening questionnaires that identify potential contraindications. Guides' supervision need not be by a person with advanced credentialing, as administration sessions are normally "non-directive."
2. It should be governed by informed consent principles. The potential harms of most psychedelics for most people are lower than but different from alcohol and nicotine, which we trust adults to use responsibly without excessive paternalism.
3. It should embrace or allow psychedelic use in a community-based paradigm, making liberal use of peer support in preparation, administration, and integration services. Peer support and group administration sessions are the best ways to promote affordability, cultural sensitivity, and inclusivity within any "scalable" psychedelic ecosystem. Early research is showing community-based paradigms may even be more efficacious than more clinical paradigms.
4. It should avoid over-regulating psychedelic substances. Oregon provides a cautionary example. A gram of *Psilocybe cubensis* mushroom under the Oregon Psilocybin Services Act sells for an average of $40-50, and doses commonly range from 3-4 grams. By contrast, unregulated *cubensis* mushrooms sell for approximately $8/gram. More people will avail themselves of the regulated system if they consider its costs justifiable when compared with the costs of unregulated (i.e., black or grey market) access. Despite the high costs of psilocybin in Oregon's and Colorado's programs, the proposed New Mexico testing rules are dramatically more onerous and costly. The harms sought to be avoided by draft rule 7.35.2.19 have not materialized in Oregon or

[1] Griffiths R, Richards W, Johnson M, McCann U, Jesse R. Mystical-type experiences occasioned by psilocybin mediate the attribution of personal meaning and spiritual significance 14 months later. J Psychopharmacol. 2008 Aug;22(6):621-32. doi: 10.1177/0269881108094300. Epub 2008 Jul 1. PMID: 18593735; PMCID: PMC3050654

Colorado, and appear to be of exaggerated concern in light of the exclusionary impacts it will have on low- and middle-income communities.

Psychedelics are not a conventional Western medicine and do not fit easily into Western models of praxis. Current attempts at combining psychedelics with Western medicine has researchers attempting to induce mystical-type experiences in a doctor's or therapist's office. It sounds absurd because it is absurd. Mystical experience has long been the province of religious and Indigenous communities wherein a person leads or facilitates such experiences in the context of a supportive community. Any equitable model of services-based access will allow for services that more closely resemble religious or Indigenous paradigms of access than the traditional models of Western clinical or medical practice.

2. Intersections of Medical and Religious Use

From our perspective, one of the most critical questions facing Medical Psilocybin Act ("MPA") rulemakers is around what kind of attitude the MPA regulations will express toward religious use cases. While the MPA does not mention the religious use of psilocybin, legal psilocybin access through the MPA co-exists alongside the legal access by sincere religious practitioners in New Mexico; we strongly believe that regulations should acknowledge this and not disregard religious adherent's claim to legal access.

In 2013, New Mexico adopted broad religious freedoms that allow religious practitioners to use psilocybin and other psychedelics as part of sincere religious exercise. NM Stat § 28-22-3 *et seq.* Additionally, regardless of the religious freedoms that the State has intentionally enacted, the passage of the MPA has created new federal protections for entheogenic religious practitioners in New Mexico. By passing MPA, New Mexico created a system for granting individualized exceptions to the NM Controlled Substances Act. When a state adopts a system for granting individualized exemptions to any law, the First Amendment to the United States Constitution requires that exemptions to that law also be granted for religious practitioners.[2] This means that a state cannot authorize legal access to a drug for medical reasons without also authorizing legal access to that drug[3] for religious reasons.

[2] *See, e.g., Tandon v. Newsom,* 593 U.S. 61 (2021); *Roman Catholic Diocese of Brooklyn v. Cuomo*, 592 U.S. _ (2020); *Fulton v. City of Philadelphia*, 593 U.S. 522 (2021).

[3] It is unclear whether allowing the medical use of psilocybin requires New Mexico to allow the religious use of only psilocybin, or whether it would require the State to permit the religious use of any drug covered under the New Mexico Controlled Substances Act. The district court in *Jensen, infra,* suggested in dicta that it would require allowing the religious use of only the specific drugs that have been legalized for medical use, but that reasoning appears at odds with the U.S. Supreme Court's decisions in *Tandon, supra,* which was not raised by the parties in that case.

This issue was recently litigated in *Jensen v. Utah County*, US Dist. Court for the Dist. of Utah, Case No. 2:24-cv-00887-JNP. In that case, a federal trial-level judge in Utah evaluated whether the Utah Controlled Substances Act was "generally applicable" despite an exception to the Utah CSA that allows health care systems to develop behavior health treatment programs using psilocybin and MDMA. The judge ruled that the Utah CSA was not generally applicable with respect to psilocybin and found that the First Amendment protects religious activities involving psilocybin in Utah. This issue is currently under review at the 10th Circuit Court of Appeals and a favorable ruling is expected for the religious claimants.

While we do not have particular recommendations with respect to this round of draft rules, we urge DOH to be proactive in not undermining or delegitimizing religious practitioners in its policies and regulations.

3. Sale Restrictions and Federal Tax Consequences

Service providers operating under Oregon's and Colorado's psilocybin programs have encountered a significant federal tax problem arising from Section 280(E) of the Internal Revenue Code. Section 280(E) prohibits any business engaged in the trafficking of a Schedule I controlled substance from deducting ordinary business expenses on their federal taxes. Because psilocybin remains in Schedule I under federal law, businesses with any direct involvement in handling or transferring psilocybin are exposed to this restriction, meaning they pay federal income tax on gross revenue rather than net income, dramatically increasing their effective tax burden.

Both Oregon and Colorado operate supervised-use models similar to the one New Mexico is building. In those state programs, psilocybin is not sold directly to program participants through a dispensary model, but is instead transferred to service centers that administer it to participants under supervision. It is precisely this transfer — from producer to service center — that triggers 280(E) exposure for the service center. Operators in both states have attempted to minimize the impact of 280(E) on their businesses by creating separate legal entities to isolate plant-handling activities from their broader business operations, so that 280(E) liability does not contaminate the tax treatment of the entire enterprise. This strategy for managing tax liability has not been evaluated by courts yet, and it is uncertain whether this approach would survive such scrutiny. Even if that approach is ultimately allowed, it is a costly and administratively burdensome strategy that disadvantages smaller operators and adds overhead to an already highly-regulated industry.

While the MPA explicitly authorizes Gross Receipts Tax deductions under state law, that provision has no effect on federal tax obligations. New Mexico operators will face the same 280(E) exposure as their counterparts in Oregon and Colorado unless the program is structured to minimize it. As drafted, the regulations replicate the same sale structure that has created these problems elsewhere, and do not take advantage of an opportunity unique to the rulemaking process to build in structural flexibility before the problem materializes. Allowing direct sales from producers to patients, while at an approved location and while under the supervision of a guide, would dramatically reduce the impact of Section 280(E) while also avoiding diversion and related concerns.

Proposed Amendments:

> 7.35.2.10(B)(7): "A producer shall: ...Only sell psilocybin or psilocybin products to other producers and to practitioners, or to program participants through the supervised sale and consumption provisions of these regulations; and only otherwise distribute psilocybin or psilocybin products to medical psilocybin testing laboratories, or to department employees for testing in accordance with this rule."
>
> [INSERT CITATION] Supervised Sale and Consumption: Direct sale of psilocybin to program participants is permitted only at an approved location on the day of the participant's administration session. Consumption of psilocybin sold directly to a program participant is permitted only in the presence of a licensed clinician or guide at an approved location on the day of sale, and only for the amounts that are to be consumed by the participant in that administration session.
>
> *What This Achieves:*

The proposed amendment introduces a direct participant sale option as an alternative pathway alongside the existing producer-to-practitioner transfer model. Under this pathway, a producer may sell psilocybin directly to a program participant — rather than to a service center — provided that the sale occurs at an approved location on the day of administration and that consumption takes place in the presence of a licensed clinician or guide. The supervised-use character of the program is fully preserved: this is not a dispensary model, and psilocybin cannot be taken off-site or consumed outside of a supervised clinical setting.

The tax consequence of this structural change is significant. When the sale runs directly from producer to participant, the service center is not a party to the transfer of the substance and is therefore not engaged in trafficking under Section 280(E).

The service center's revenue becomes clearly separable from the medicine-handling transaction, allowing those businesses to deduct ordinary operating expenses and reducing the tax penalty that would otherwise fall on the program's clinical infrastructure.[4]

This amendment does not require operators to use the direct sale model but it does create an option. Operators who prefer the traditional transfer structure from cultivator to guide may continue to use it. But providing this pathway gives New Mexico's licensed cultivators and healing centers a tool to navigate federal tax exposure that operators in other states have had to engineer around after the fact, at significant cost. Building this flexibility into the regulations now, before the program issues its first licenses, is precisely the kind of forward-looking regulatory design that will determine whether New Mexico's program remains viable and accessible over time.

4. Anticipating and Reducing Negative Consequences of Profit Motives in the State Program

The healing potential of psilocybin is both profound and vulnerable to exploitation. As with any new state-created market, not all who seek to participate will be motivated by concern for the public interest. Some will be motivated primarily by profit, and a smaller number will seek to exploit the program's regulatory gaps for financial gain at the expense of operators, patients, and the program's long-term integrity. It is the responsibility of regulators to design a framework that supports good-faith actors and limits the ability of bad-faith actors to cause harm, and to do so before those actors have the opportunity to entrench themselves in the program's infrastructure. These concerns are exacerbated by New Mexico's lack of prohibitions around the corporate practice of medicine.

As currently drafted, the regulations governing ownership, control, and permit-transfer fall short of that goal in two directions simultaneously. The restrictions are broad enough to burden legitimate arrangements (including friends-and-family investment, minority ownership stakes, and other financing structures that small operators depend on) while leaving the more sophisticated disguised control mechanisms that present the greatest patient safety risk inadequately addressed. This is a foundational gap that will have lasting consequences for the program if it is not corrected before the first permits are issued.

[4] This amendment specifically addresses federal tax consequences, which is far from the only liability consideration for operators under the state program. For other liability reasons, it may still be advisable for the service center to create and operate under separate legal entities for the distinct scope of services provided.

7.35.2.9 B. prohibits a person from holding an ownership interest in a permittee shall not hold an ownership interest in any other permittee. We support limiting the permittees to holding an interest in only one producer permit, and not allowing a person to hold interests in both producer and testing permits. However, once additional regulations are adopted concerning psilocybin administration and other aspects of the program, we hope that DOH will not prohibit producers from also functioning as a guide or serving other roles within the program.

Draft rule 7.35.2.26 (C)(m) subjects permittees to disciplinary action if DOH finds that a permittee has passive investors who do not enjoy "the customary incidents of ownership." This is an unclear standard that would appear to penalize permittees who have passive investors in their operations that do not carry decision-making authority. This would be problematic in light of the available pool of funding that is available to federally-illegal businesses.

> 7.35.2.26 (C)(m): "Disciplinary action may be taken against a permittee or a permit-applicant. Disciplinary action may consist of revocation, or suspension in whole or in part, of a permit, denial of an application for a permit, and other actions. Disciplinary action may be imposed based on: … a finding by the department that any person holds an ownership interest in a permit or permittee that is nominal or without the benefits and risks of genuine ownership."
>
> 7.35.2.7 (G)(1): "'Genuine ownership' means an ownership interest in an applicant or a permittee that is evidenced by record ownership in which the owner, regardless of the amount of capital or assets that the owner contributes to the applicant or permittee, enjoys the customary incidents of ownership and shares in the profits and losses of the permittee proportionate to the percentage of the owner's interest in the permit."

Proposed solution: clarify that passive investments are allowed within the program. Particularly where there are no prohibitions on the corporate practice of medicine, requiring all investors to have decision making authority can result in "mission drift" and undermine the medical goals of the program. Ideally, business decisions will be made by people who are actively involved with provision of care, lest the medical aims of the program be overridden by financial motives.

5. Restrictors for Property-Renting Applicants

We support the comment submitted by Healing Advocacy Fund and Rudick Law Group regarding the requirements for property renter cultivators at 7.35.2.8(A)(9). The prior comment proposes a two-part amendment: first, adding a lease agreement

(with an anti-liability waiver) pathway as a new alternative to the existing proof-of-ownership and written approval options; and second, revising the scope of the written approval option to require only attestation of permission to participate in a licensed Department of Health program, rather than permission to cultivate psilocybin on the premises. We write to emphasize that both components of that amendment are necessary, and to caution the Department against adopting the revised attestation language without also adopting the lease agreement pathway.

The revised attestation language addresses a legal exposure problem. Requiring a landlord to attest in writing to permitting the cultivation of a Schedule I substance on their premises, even in the context of a state-licensed program, exposes that landlord to potential civil and criminal liability. Narrowing the attestation to program participation rather than cultivation directly reduces that exposure and makes the written approval pathway viable for landlords who are willing to support their tenants but cannot sign a document that could be characterized as approving federally illegal activity.

The lease agreement pathway is also a necessary addition. The Department can provide a lease agreement option that still requires the lease to adequately protect the cultivators right to participate in the program by requiring an anti-illegality waiver in the lease. Both are necessary. A revised attestation still requires a landlord to execute a standalone written document outside of the lease relationship. Some landlords will not be willing to provide any freestanding written approval for activities involving a controlled substance, however carefully worded. Many will prefer to incorporate terms directly into the lease, and regulations should allow that option.

Respectfully Submitted,

Jonathan M. Dennis
On behalf of PBA New Mexico Working Group

Public Comment on Proposed Rule 7.35.2 NMAC

Producer and Laboratory Requirements, New Mexico Medical Psilocybin Program

Submitted by: Gregory Evans, Independent Researcher and Contributing Member, MPAB Propagation Committee
Contact: gregory.L.evans@gmail.com
Re: Proposed adoption of 7.35.2 NMAC, published for committee review 3/24/2026
Hearing Scheduled: April 24, 2026, Harold Runnels Building, Santa Fe, NM

Introduction

My name is Gregory Evans. I am an independent researcher and home mycologist based in Santa Fe, New Mexico, and a contributing member of the Medical Psilocybin Advisory Board's Propagation Committee. I submit these comments on proposed rule 7.35.2 NMAC in that capacity.

This public comment addresses deficiencies in the proposed rule's definitions, testing framework, potency reporting, and related provisions. Each section identifies the original rule language, the specific problem, a suggested amendment, and the rationale supporting the change.

These comments aim to ground the rule in accurate science, operational workability, and alignment with the board's adopted recommendations.

I. Definitions

A. Definition Amendments

1. §7.I.2 "Inoculate" — Biological Inaccuracy

Original rule language:

> *"Inoculate" means the process of introducing psilocybin spores of mycelium into growth medium.*

Problem: "Psilocybin spores" is biologically inaccurate: spores do not contain psilocybin. The definition restricts inoculation to one organism type.

Suggested amendment:

> *"Inoculate" means the process of introducing spores, mycelium, or spawn into growth medium.*

Why: Separates the inoculation definition from organism scope. Species limitation remains at §7.P.12 and §7.P.11.

2. §7.P.10 "Psilocybin" — Bundled Compound Creates Regulatory Ambiguity

Original rule language:

> *"Psilocybin" means the naturally occurring psychedelic compound 4-phosphoryloxy-N,N-dimethyltryptamine, also known as 4-PO-DMT, and its pharmacologically active metabolite psilocin, 4-hydroxy-N,N-dimethyltryptamine, found in certain mushrooms, but does not include synthetic or synthetic analogs of psilocybin.*

Problem: Psilocybin and psilocin are separate molecules with different CAS numbers, molecular weights, and pharmacokinetic roles. Bundling them into one definition contradicts §7.P.6, Table 2, and §14.A.4.h, all of which treat them as distinct analytes.

Suggested amendment:

> *"Psilocybin" means the naturally occurring psychedelic prodrug 4-phosphoryloxy-N,N-dimethyltryptamine (CAS 520-52-5), also known as 4-PO-DMT, found in certain mushrooms, but does not include synthetic psilocybin or synthetic analogs of psilocybin.*

> *"Psilocin" means the pharmacologically active metabolite 4-hydroxy-N,N-dimethyltryptamine (CAS 520-53-6), produced by dephosphorylation of psilocybin.*

Why: Separating the definitions resolves internal contradictions between §7.P.6, Table 2, and §14.A.4.h. Labs report each compound on its own line. CAS numbers anchor each term to its molecule.

3. §7.C.7 / §7.M.1 "Cultivation" and "Manufacture" — Overlapping Scope

Original rule language (§7.C.7):

> *"Cultivation" means the growing, harvesting, drying, and handling of psilocybin-producing mushrooms.*

Original rule language (§7.M.1):

> *"Manufacture" or "process" means to harvest, dry, compound, convert, or package into pills, capsules, or sachets of homogenized powder, and label mushrooms and products containing psilocybin.*

Problem: Harvesting and drying appear in both definitions. A producer performing either act is simultaneously "cultivating" and "manufacturing," triggering conflicting obligations. The rule never identifies when a cultivation batch becomes manufacturing input, breaking the traceability chain §15 requires.

Suggested amendment:

> *"Cultivation" means the inoculation, growing, and maintenance of psilocybin-producing mushrooms through harvest.*

> *"Process" means to perform one or more of the following post-harvest operations on psilocybin mushrooms or psilocybin material: drying, homogenizing, or preparing processed material for storage. Processing concludes when the material is in a stable, storage-ready state. For tailored dosage preparation, see "compound" (§7.C.5).*

> *"Manufacture" means to prepare a finished psilocybin product from processed psilocybin material by enclosing, forming, or assembling it into a dosage form authorized by the department. Manufacturing operations under this rule are limited to encapsulation, sachet packaging, or other packaging of homogenized powder (see §11).*

This amendment omits §7.C.6 ("convert"). The current rule defines it as "converting psilocybin mushrooms into a homogenized lot," which is redundant with homogenization. Its common meaning implies extraction, which §11 does not authorize.

Why: Draws a clean boundary at harvest: cultivation stops, processing begins. Process fills the post-harvest gap. Manufacture is scoped to §11's authorized forms.

---

4. §7.P.6 "Potency" — Required Analytes Unspecified

Original rule language:

> *"Potency" means the level of psilocybin and analytes in a sample of a batch, lot, or product which is measured and expressed in metric units.*

Problem: "Analytes" is unspecified. Two labs testing the same sample could report different analyte panels. Table 2 already lists the intended analytes with CAS numbers; the definition fails to reference it.

Suggested amendment:

> *"Potency" means the concentration of the analytes specified in Table 2 of §19.G in a sample of a homogenized lot, measured and expressed in milligrams per gram (mg/g).*

Why: Anchors "analytes" to Table 2 so every lab reports the same panel. mg/g replaces the vague "metric units." If the department updates Table 2, the potency definition tracks automatically.

5. §7.M.3 "Mycelium" — Unnecessary Species Qualifier

Original rule language:

> *"Mycelium" means the fungal threads or hyphae of psilocybin containing mushrooms.*

Problem: Mycelium is a universal fungal structure. Restricting the term excludes contaminating organisms (*Trichoderma*, *Aspergillus*, *Penicillium*) whose mycelium the rule may need to reference.

Suggested amendment:

> *"Mycelium" means the vegetative body of a fungus, composed of a network of filamentous structures called hyphae.*

Why: Removes the species constraint so the rule can reference mycelium accurately in any context. Program scope is already established by §7.P.12 and §7.P.11.

---

6. §7.F.3 "Fruiting Bodies" — Reduced to Single Function

Original rule language:

> *"Fruiting bodies" means the spore producing organs of the fungi.*

Problem: Scientifically inaccurate. A fruiting body is the reproductive structure of a fungus, not a "spore producing organ." Spores are produced by specialized cells borne on tissues within the fruiting body. The definition also reduces the fruiting body to a single function, rather than the material harvested, dried, tested, and administered under this rule.

Suggested amendment:

> *"Fruiting body" means the spore-bearing reproductive structure of a fungus, including associated tissues.*

Why: More biologically accurate, better aligns with §7.M.4, and more clearly describes the material regulated under this rule.

---

7. §7.C.8 / §7.H.2 / §7.H.5 / §7.P.8 Lot Hierarchy — Definitions Do Not Enforce the Intended Chain

Original rule language (§7.C.8):

> *"Cultivation batch" or "Batch" means a quantity of unharvested spores, fruiting body, or mycelium that is grown together under the same conditions, that may contain fungi that originates from diverse spores or mycelial tissue.*

Original rule language (§7.H.2):

> *"Harvest lot" means the fruiting bodies of mushrooms cultivated and harvested at the permitted location.*

Original rule language (§7.H.5):

> *"Homogenized lot" means a quantity of psilocybin mushrooms identified by a producer that is cultivated and dried under the same conditions, and harvested within a specified time period at the same location within permitted premises.*

Original rule language (§7.P.8):

> *"Product lot" means the same type of product that has been created from a homogenized lot.*

Item 7 (continued): Lot Hierarchy

Problem statement:

§15.A requires producers to track cultivation batches, harvest lots, homogenized lots, product lots, and psilocybin product inventory. §15.A.1 assigns UIDs to cultivation batches, homogenized lots, and product lots. The definitions do not connect the stages to one another. Six gaps:

1. Chain broken. §7.H.2, §7.H.5, and §7.P.8 do not name their parent stages.
2. Mixed genetic origin permitted. §7.C.8 allows "fungi that originates from diverse spores or mycelial tissue."
3. Homogenization not required. §7.H.5 does not reference §7.H.4.
4. Product lot underspecified. "Same type of product" is undefined.
5. UID lists inconsistent. §10.A.6 lists harvest/homogenized/product. §15.A.1 lists cultivation/homogenized/product.
6. Dead clause. "Harvested within a specified time period" in §7.H.5 has no value assigned.

Suggested amendment:

> *"Cultivation batch" or "batch" means the fruiting bodies produced from a single inoculation event in which spawn derived from a single genetic source is introduced to bulk growth medium, under the same environmental conditions, at the permitted location. Each cultivation batch shall be assigned a unique identification number.*

> *"Harvest lot" means the dried fruiting bodies harvested from a specific cultivation batch at the permitted location. A harvest lot may include material from one or more flushes, provided all material originates from the same cultivation batch. Fruiting bodies shall be dehydrated prior to storage. Each harvest lot shall be assigned a unique identification number.*

> *"Homogenized lot" means a quantity of dried psilocybin fruiting bodies from one or more harvest lots originating from the same cultivation batch that have been homogenized in accordance with Paragraph (4) of this subsection. A homogenized lot is the testable unit for all required testing under Section 19. Each homogenized lot shall be assigned a unique identification number and a homogenization date under Paragraph (3) of this subsection.*

> *"Product lot" means a quantity of a single product form (capsules, sachets, or packaged homogenized powder) produced from a specific homogenized lot. If multiple product forms are created from the same homogenized lot, each form constitutes a separate product lot. Each product lot shall be assigned a unique identification number and shall inherit the test results and identification lineage of its parent homogenized lot.*

Why: The amended definitions chain each stage to its parent, constrain genetic origin, require homogenization per §7.H.4, specify product form per §11, and resolve the §10.A.6/§15.A.1 UID inconsistency at the definitional level.

8. §7.U "Unique Identification Number" — Permissive Scope

Original rule language:

> *"Unique identification number" means the most recent unique number assigned by traceability for a psilocybin product that may include cultivation batches, harvest lots, homogenized lots, product lots, and testing samples.*

Problem: "May include" makes UID coverage permissive. A producer cannot tell whether UID assignment at any given stage is required or optional.

Suggested amendment:

> *"Unique identification number" means a unique number assigned within the traceability system to a cultivation batch, harvest lot, homogenized lot, or product lot. Each production stage shall retain its assigned unique identification number; subsequent stages receive new unique identification numbers while preserving the identification lineage of their parent stage. The department may, by guidance or order, designate additional lot or sample categories for which unique identification numbers shall be assigned.*

Why: Makes assignment mandatory and aligns §7.U with the four production stages. Follows the §19.E.1 pattern: enumerated baseline plus department authority to expand.

B. Definition Gaps

Terms not currently defined in §7 that are needed for operational clarity.

9. §7.S "Spawn" — Recommended Addition

Gap: The amended "inoculate" definition (Item 1) references spawn. Spawn is mycelium-colonized substrate used to inoculate bulk growth medium, the standard inoculation method and the first link in the §15 traceability chain.

Recommended definition:

> *"Spawn" means a substrate material colonized by mycelium that is used as an inoculant to initiate mushroom cultivation in bulk growth medium.*

Why: Anchors the inoculate definition (Item 1), supports §12.C and §15 traceability, and aligns with the batch definition's origin constraint (Item 7).

---

10. §7.C "Certificate of Analysis" — Recommended Addition

Gap: §19 requires testing with pass/fail criteria. §19.K.2 references "a certificate of analysis" but the term is never defined in §7. Without a definition, the COA has no required content, format, or minimum information standard.

Recommended definition:

> *"Certificate of analysis" or "COA" means a document issued by a permitted psilocybin testing laboratory that reports the results of all analyses performed on a batch sample pursuant to this rule. A certificate of analysis shall include, at minimum: the batch unique identification number; the name and permit number of the testing laboratory; the name and permit number of the producer; the date of sample collection; the date of analysis; the results of each required test expressed in the units specified by this rule; a pass or fail determination for each test with an established action level; and the signature or electronic certification of the laboratory director or authorized representative.*

Why: §19.K.2 assumes a COA exists but §7 never defines it. Minimum contents consolidate information already required by §19, §14.A.4, and §15.

11. §7.S "Shelf Life" — Recommended Addition

Gap: §14.A.4.j requires an expiration date on every label. §7.E defines "expiration date" but the rule never defines how a producer determines that date. No shelf life definition, no stability testing requirement, no methodology.

Recommended definition:

> *"Shelf life" means the period of time, not to exceed twelve months from the date of batch homogenization, during which a psilocybin product is expected to maintain its labeled potency, purity, and safety when stored under the conditions specified by the producer on the product information document.*

Why: Anchors shelf life to homogenization date (§7.H.3), labeled potency (§14.A.4.h), and producer-specified storage conditions. The twelve-month ceiling reflects the board's adopted framework (§VI.B, February 27, 2026).

12. §7.S "Stability" — Recommended Addition

Gap: Stability is the empirical basis for shelf life. The rule requires retesting (§19.L.2) but does not frame this as stability testing and does not require the data to inform shelf life or expiration date determination.

Recommended definition:

> *"Stability" means the demonstrated capacity of a psilocybin product to maintain its labeled potency, purity, and microbial safety within the limits established by this rule over the course of its shelf life when stored under the conditions specified on the product information document.*

Why: §19.L.2 already generates stability-relevant data. Defining stability connects retest data to shelf life determination (Item 11) and closes the retest-to-expiration gap.

C. Definitions to Defer

Terms defined in §7 whose operative scope falls outside producer/lab regulation. These should be finalized in the appropriate committee's rulemaking process, not in 7.35.2 NMAC. No amended language is proposed.

Item	Section	Term	Defer to
13	§7.A.2	Administration Session	DACP / clinical practice
14	§7.A.6	Approved Location	DACP / facility licensing
15	§7.C.2	Certification	DACP / Training & Education
16	§7.C.3 / §7.P.7	Clinician / Practitioner	DACP / clinical practice
17	§7.G.3	Guide	Training & Education
18	§7.M.2	Medical Services	DACP / clinical practice
19	§7.Q.1 / §7.Q.2	Qualified Patient / Qualifying Condition	Patient Qualification & Safety
20	§7 (undefined)	Dose / Dosage	DACP / clinical practice

(End of Section I. Definitions)

II. Testing

A. Moisture Control

21. §19.F Water Content Testing — No Action Level Defined

Problem: Water content testing lacks a fail condition. Potency reporting and shelf life depend on water content. Without a threshold, every downstream calculation starts from an unvalidated number.

Suggested amendment (add to §19.F):

> *Water content shall be determined by loss on drying (LOD) and shall not exceed 10% by weight. The water content result, expressed as a percentage, shall be reported on the certificate of analysis. A homogenized lot that exceeds 10% water content shall not be released for sale or distribution for consumption. Water content retesting shall be conducted in accordance with the retesting provisions of §19.L.2.*

Why: 10% is the potency and shelf stability ceiling: below it, alkaloid degradation is reduced. LOD validates the 12-month shelf life claim (Item 11). Water activity (Item 22) handles microbial safety separately.

Refer to Addendum A.

---

22. §19 New Subsection — Water Activity (New Provision)

Problem: §19.E tests organisms on finished product but does not regulate the moisture condition enabling growth. Below a_w 0.60, no pathogen, yeast, or mold relevant to this matrix can grow. §19.F measures total moisture; water activity measures the fraction available to biology. Both are needed.

Suggested amendment (add following §19.F):

> ***Water activity testing.*** *A producer shall arrange for a sample of each homogenized lot to be collected and tested by an approved psilocybin testing laboratory for the purpose of water activity testing, prior to the lot being released for sale or distribution for consumption. A sample shall pass if the measured water activity does not exceed 0.60 a_w. Water activity shall be measured using a method validated to ±0.02 a_w precision. The water activity result shall be reported on the certificate of analysis.*

Why: 0.60 a_w is below the growth floor of every panel organism. ~$15-25 per sample. With §19.F and §7.S shelf life, water activity completes the moisture control framework.

B. Microbiological Panel

> Organism-by-organism risk analysis, regulatory precedent review, water activity growth thresholds, and per-sample cost assessment are documented in **Addendum B**. Per-organism analysis in **Addendum C**.

23. §19.E Microbiological Panel — Scope, TYM, and Aspergillus Reporting

Problem:

1. Panel scope. Four organisms (STEC, *C. botulinum*, *P. aeruginosa*, *Trichoderma*) lack evidence basis for dried psilocybin mushroom biomass; three more (*Listeria*, *A. niger*, *A. terreus*) fall outside USP <2023> for this product category.

2. Total Yeast and Molds. The product is a dried fungus. A TYM test on fungal biomass measures the target organism itself; no threshold distinguishes contaminated from normal.

3. Aspergillus reporting. The four species carry different risk profiles. §19.E.2 permits collective reporting, so an *A. flavus* detection is indistinguishable from *A. niger* on the COA.

Suggested amendment:

1. Replace Table 1:

Target Microbe	Action Level
E. coli (generic)	100 CFU/g
Aspergillus flavus	Present
Aspergillus fumigatus	Present
Salmonella spp.	Present

2. Amend §19.E.1 (Evidence-triggered authority): The department may require testing for STEC, *C. botulinum*, *P. aeruginosa*, *L. monocytogenes*, *Trichoderma*, *A. niger*, *A. terreus*, TAMC, and TYM if quality control testing, facility inspection, or epidemiological evidence identifies a specific contamination concern. Written notice to affected producer required.

3. Replace §19.E.2: Aspergillus species listed in Table 1 shall be reported on a separate line.

Why: Reduces routine panel to four organisms supported by USP <2023>. Remaining organisms route to §19.E.1. Individual Aspergillus reporting distinguishes aflatoxin risk from invasive risk. TYM is uninterpretable on fungal biomass.

> **A Common Confusion:** *Aspergillus* is not black mold. The organism colloquially called black mold is *Stachybotrys chartarum*, a separate genus that colonizes water-damaged building materials, not a food contaminant.

C. Retest Cadence

24. §§19.E / 19.G Retest Cadence — Duplicative Language

Problem: The retest cadence appears in four provisions (§19.E, §19.F, §19.G, §19.L.2), each restating the same interval independently. A single policy change requires four amendments.

Suggested amendment: Strike the retest sentence from §19.E and §19.G. Replace each with:

> *Re-testing shall be conducted in accordance with §19.L.2.*

Why: Consolidates in §19.L.2. A future amendment modifies one provision, not four. Takes no position on the interval itself.

Rule ref: §19.E, §19.G, §19.L.2

D. Sampling and Scope

25. §19.B.1 Sample Size — Fixed Range Conflicts with Laboratory Requirements

Original rule language:

> *Samples shall be between 1-5 grams for every 1 kilogram of product in each homogenized lot and in accordance with the psilocybin testing laboratories sampling protocols.*

Problem: §19.B.1 caps samples at 1-5 grams and defers to lab SOPs in the same sentence. A validated method requiring more than 5 grams has nowhere to land. No USP, ISO/IEC 17025, or cannabis program fixes a gram range across tests.

Suggested amendment:

> *The producer shall provide a sample of sufficient quantity, as determined by the testing laboratory's validated standard operating procedures, to complete all analyses required by this rule. The testing laboratory shall document its minimum sample size requirements for each required test and shall communicate the total sample size needed to the producer prior to collection. The testing laboratory shall collect only the minimum quantity necessary to perform all required analyses, including any retention sample the laboratory's protocols require.*

Why: SOP deference removes the fixed ceiling and lets sample size track what §19 requires.

---

26. §§10.A.2, 13, 20.B, 21.A Residual Solvents — References Not Applicable to Authorized Product Forms

Problem: §11 authorizes capsules, sachets, and homogenized dried powder. No provision authorizes solvent-based extraction or concentration. The four solvent references carry over from cannabis rulemaking.

Suggested amendment: Strike solvent references from §10.A.2, §13, §20.B, and §21.A. Replace with cleaning-agent language where applicable. If the department later authorizes extracted product forms, solvent controls attach to that authorization.

Rule ref: §10.A.2, §11, §13, §20.B, §21.A

III. Batch and Production

27. §10.A.6 UID Assignment — Omits Cultivation Batch

Original rule language:

> *Associate every harvest lot, homogenized lot, and product lot with a unique identification number and enter this information into the traceability system.*

Problem: Omits cultivation batches. A producer reading §10 alone skips UID assignment at the first production stage.

Suggested amendment:

> *Associate every **cultivation batch,** harvest lot, homogenized lot, and product lot with a unique identification number and enter this information into the traceability system.*

Why: Aligns §10.A.6 with §7.U (Item 8) and §15.A.1 (Item 28). All four stages: cultivation batch, harvest lot, homogenized lot, product lot.

---

28. §15.A.1 UID Assignment — Omits Harvest Lot

Original rule language:

> *each cultivation batch, homogenized lot, and product lot shall be assigned a unique identification number in the traceability system*

Problem: Omits harvest lots. A producer reading §15 alone skips UID assignment at the stage between cultivation and homogenization.

Suggested amendment:

> *each cultivation batch, **harvest lot,** homogenized lot, and product lot shall be assigned a unique identification number in the traceability system*

Why: Aligns §15.A.1 with §7.U (Item 8) and §10.A.6 (Item 27). Consistent four-stage UID assignment across §§7, 10, and 15.

IV. Labeling and Potency

29. §14.A.4.h / §19.G Potency Calculation — "Total Psilocybin Equivalent" and "Total Potential Psilocin" Undefined

Problem: §14.A.4.h requires two calculated values but the rule omits conversion factors, analyte inputs, and calculation formula. Two laboratories testing identical samples report different label values.

Suggested amendment (add to §19.G):

> *The department shall require, as a condition of laboratory permit approval or renewal under §8.C, that each psilocybin testing laboratory's standard operating procedures include a validated methodology for calculating "total psilocybin equivalent" and "total potential psilocin" as referenced in §14.A.4.h. The department shall specify, by guidance or order, the conversion factors, analyte inputs, and calculation formula to be used by all permitted laboratories. No laboratory shall report "total psilocybin equivalent" or "total potential psilocin" values using a methodology that has not been reviewed and approved by the department.*

Why: Potency calculation is a technical standard that belongs in the SOP approval process (§8.C), where it can be validated, standardized, and updated without a rule amendment. Every permitted lab uses the same formula.

Rule ref: §14.A.4.h, §19.G, §8.C

Closing

These comments are submitted in good faith, grounded in the Propagation Committee's adopted framework, the Advisory Board's unanimous vote of February 27, 2026, and the best available science on psilocybin mushroom cultivation, testing, and product safety. The goal throughout is a rule that protects patients, supports producers and laboratories, and reflects what the board actually recommended.

Where specific amendments are proposed, they are offered as starting points for discussion, not final positions. Where definitions are flagged for deferral, the intent is to preserve the work of the committees responsible for those domains. Where costs are cited, they are estimates intended to ground the conversation in operational reality.

New Mexico has an opportunity to build a psilocybin regulatory framework that is scientifically rigorous, operationally practical, and worthy of the public trust placed in this program. I respectfully urge the Department to consider these comments in that spirit.

Respectfully submitted,

Gregory Evans
Independent Researcher and Home Mycologist
Contributing Member, MPAB Propagation Committee
Santa Fe, New Mexico

Public Comment on Proposed Rule 7.35.2 NMAC

Document Package Summary

Submitted by: Gregory Evans, Independent Researcher and Contributing Member, MPAB Propagation Committee
Hearing: April 24, 2026, Harold Runnels Building, Santa Fe, NM
Contact: gregory.L.evans@gmail.com

Document Package

Document	Pages	Scope
Public Comment	11	29 items across definitions, testing, batch/production, and labeling. Original rule language, problem, amendment, and rationale for each.
Addendum A Moisture & Water Activity	5	Working analysis on moisture content standards, LOD vs. water activity, dosage deviation, USP <731>, lab workflow, and microbial panel linkage.
Addendum B Microbiological Panel	8	Risk analysis and cost assessment for §19.E Table 1. Panel routing, pharmacopeial anchors, structural authorities, cost comparison, compliance-triggered framework.
Addendum C Per-Organism Analysis	3	Target-by-target analysis for all nine organism categories. Biology, exposure-route reasoning, USP alignment, and routing recommendation for each.

Summary of Amendments by Category

I. Definitions (Items 1-20)

Eight amendments correct biological inaccuracies, separate bundled compounds, resolve overlapping definitions, enforce the lot hierarchy chain of custody, and make UID assignment mandatory. **Four new definitions** fill operational gaps: spawn, certificate of analysis, shelf life, and stability. **Eight definitions deferred** to the committees responsible for clinical practice, patient qualification, and dosage.

II. Testing (Items 21-26)

Water content: Add 10% LOD ceiling and pass/fail reporting on the COA (Item 21).

Water activity: New §19 provision requiring $a_w \leq 0.60$, the upstream preventative control that validates every downstream microbial safety claim. ~$15-25/sample (Item 22).

Microbiological panel: Reduce routine Table 1 from nine organism categories to four (*E. coli*, *A. flavus*, *A. fumigatus*, *Salmonella*), anchored to USP <2023>. Route remaining organisms to §19.E.1 triggered testing. Require individual Aspergillus reporting. Remove TYM (category-incompatible with fungal biomass). Estimated cost reduction: ~$420-800+ to ~$120-210 per release event (Item 23).

Retest cadence: Consolidate duplicative interval language into §19.L.2 (Item 24). **Sample size:** Defer to lab SOPs, remove fixed 1-5g ceiling (Item 25). **Residual solvents:** Remove four inapplicable solvent references; §11 does not authorize extraction (Item 26).

III. Batch and Production (Items 27-28)

Align §10.A.6 and §15.A.1 UID assignment lists with the four-stage production chain defined in Item 7. Add cultivation batch to §10.A.6; add harvest lot to §15.A.1.

IV. Labeling and Potency (Item 29)

"Total psilocybin equivalent" and "total potential psilocin" are required on every label (§14.A.4.h) but have no defined formula, conversion factors, or analyte inputs. Route calculation methodology to the SOP approval process at §8.C so every permitted lab uses the same formula.

> **Core position:** The proposed rule should reflect the board's adopted framework, anchor testing to USP <2023> pharmacopeial standards, enforce moisture and water activity controls that make the microbial framework work, and give the Department clear triggered-testing authority for organisms removed from routine. These amendments reduce cost, improve clarity, and do not reduce patient safety.

Moisture Content & Water Activity

Working Analysis

Addendum to Public Comment | New Mexico Medical Psilocybin Program
NMDOH Advisory Board, Propagation Committee

Prepared by Gregory Evans | April 23, 2026

Summary of Positions

Working analysis and positions reached through extended discussion on moisture content standards, water activity thresholds, testing methodology, and their downstream effects on dosage accuracy and microbial risk for the NM Medical Psilocybin Program.

- Moisture ceiling: <=10% w/w
- Practical target: 5-8% w/w
- Water activity: a_w <= 0.60
- LOD testing (USP <731>) required at lab intake
- Sample size defined by lab SOPs, not rule language
- Residual solvents panel: remove (not applicable to unextracted biomass)
- Production/drying methods: not regulated

1. Moisture Content Standards

Why It Matters

Dried psilocybin mushroom biomass is dosed gravimetrically. The patient receives a weighed amount of powder. Water mass displaces active compound mass per unit weight. Uncontrolled moisture variability directly introduces dosing error. Fresh mushrooms contain 85-95% water. Proper dehydration reduces this to single digits. The regulatory question is where to draw the line.

Established Thresholds

<=10% w/w moisture -- Maximum acceptable for storage stability. Above this, degradation accelerates and microbial risk increases. Consistent with food-grade dried mushroom standards (Codex Alimentarius) and stability data showing minimal alkaloid loss over 15 months at <10% moisture in dark, room-temperature storage (Gotvaldova et al. 2021).

5-8% w/w -- Practical operating target for well-dried biomass. Achievable with standard food dehydration equipment. Diminishing returns below 5%.

a_w <= 0.60 -- Water activity threshold below which microbial growth ceases. More functionally meaningful than moisture percentage alone because it accounts for how tightly water is bound in the matrix, not just how much is present.

Production Methods Are Not Regulated

How a producer achieves the moisture target is their decision. Drying technique, temperature, equipment, and duration are at the producer's discretion. A producer who uses aggressive high-heat methods and gets lower potency results has made a production decision, not a compliance failure. The regulation defines the outcome standard, not the process.

2. LOD vs. Water Activity: Two Measures, Two Jobs

What Each Number Measures

Water content (% LOD) measures total water mass as a percentage of sample mass. Method: USP <731> Loss on Drying (weigh, oven at 105 C, re-weigh). It answers: *how much of this powder is water instead of active compound?*

Water activity (a_w) measures the fraction of water thermodynamically available to participate in biological and chemical reactions. Scale: 0 (bone dry) to 1.0 (pure water). Method: chilled-mirror dewpoint or capacitance sensor, ~$15-25/sample. It answers: *can anything grow in this?*

The Relationship Is Nonlinear

A sample's water content and water activity are related but not proportional. The relationship is called a **moisture sorption isotherm** and depends on the matrix. In dried *Psilocybe cubensis* powder:

Moisture (% LOD)	Approx. a_w	What It Means
3-5%	0.15-0.25	Over-dried. Brittle, dusty. Functional but unnecessary.
5-8%	**0.30-0.45**	**Cracker dry. Target range.** Snap-clean breaks, no flex. Food dehydrator at 130-160 F to weight stability.
10%	~0.40-0.50	**LOD ceiling.** Well below a_w 0.60. Passes both thresholds.
12-14%	~0.50-0.58	Getting soft. Stems may bend. Approaching a_w threshold.
14-18%	0.58-0.65	**Fails a_w.** Microbial growth possible. Material pliable.
>18%	>0.65	Underdried. Storage risk. Would not pass any reasonable standard.

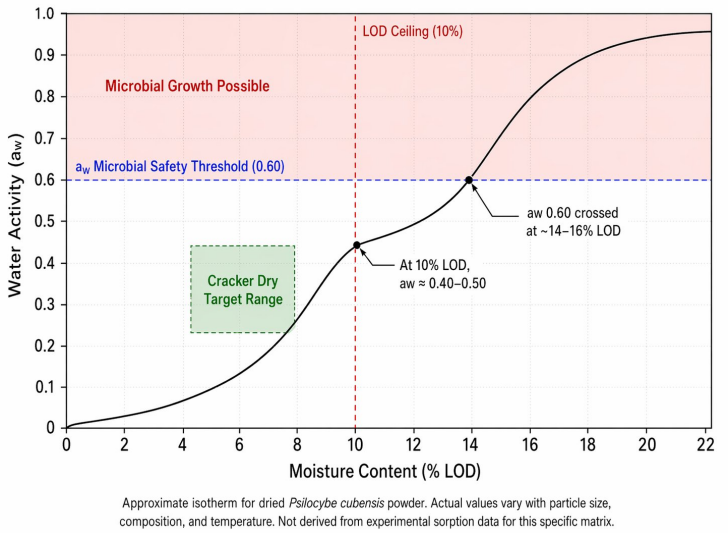

Figure 1. Approximate moisture sorption isotherm for dried Psilocybe cubensis powder. Actual values vary with particle size, composition, and temperature. Not derived from experimental sorption data for this specific matrix.

> **Key insight:** At 10% LOD, water activity is approximately 0.40-0.50, well below the 0.60 a_w safety threshold. The LOD ceiling is the tighter constraint for this matrix. If a sample passes 10% LOD, it will almost certainly pass 0.60 a_w. The a_w test catches the edge case: bad storage, incomplete homogenization, localized rehydration.

2. LOD vs. Water Activity *(continued)*

Why Both Tests Exist

LOD <= 10% is the potency and stability gate.

- Water mass dilutes the mg/g potency reading on HPLC
- LOD value is used to calculate dry-weight correction on the COA
- Below 10%, alkaloid degradation stays under 5% over 15 months in dark, room-temperature storage (Gotvaldova 2021)
- Dosing is gravimetric: water displaces active compound per unit weight

a_w <= 0.60 is the microbial safety gate.

- Below 0.60, no pathogen, yeast, or mold relevant to this matrix can grow
- Scientific basis for reducing the micro panel
- $15-25 per sample, cheapest test on the full panel
- Without a_w on every COA, the reduced-panel argument loses its foundation

Together: LOD controls potency accuracy and shelf stability. Water activity controls microbial safety. Both appear on the COA. Both have pass/fail thresholds. Different numbers, different scales, different jobs.

What 'Cracker Dry' Means in These Terms

A producer drying mushrooms to weight stability in a food dehydrator at 130-160 F will land at 5-8% LOD and approximately 0.30-0.45 a_w. The physical test: fruiting bodies snap cleanly, stipes break like dry twigs, no flex or bend. Standard practice requiring no specialized equipment beyond a food dehydrator ($50-200) and a kitchen scale.

The LOD test at the lab *confirms* what the producer already achieved through standard drying practice. Verification, not discovery. The a_w test adds microbial safety confirmation that LOD alone cannot provide.

> **Plain-language summary for non-scientists:** Think of water content as 'how wet is this powder' and water activity as 'can anything grow in it.' A sample can have some water in it (10% by weight) but have that water locked up so tightly that nothing biological can use it (a_w 0.40). The 10% LOD rule protects potency accuracy. The 0.60 a_w rule protects against microbial contamination. Both are cheap, standard lab tests. Both go on the certificate of analysis.

3. Dosage Deviation from Moisture Variability

Core Relationship

If a product is tested at moisture content M_0 and later dosed at moisture content M_1, the dosing error is:

```
Error = (1 - M1) / (1 - M0) - 1
```

The relative standard deviation (RSD) of dose attributable to moisture variability alone:

```
RSD_dose ~ sigma_M / (1 - M0)
```

Where sigma_M is the standard deviation of moisture content across the product's lifecycle.

Practical Examples

Target Moisture (M_0)	Moisture SD	Dose RSD
6%	2%	~2.13%
8%	3%	~3.26%
10%	4%	~4.44%

Compounding Error

Moisture is one of several error sources in gravimetric dosing. Total uncertainty combines via root-sum-of-squares:

```
RSD_total = sqrt( RSD_moisture^2 + RSD_homogeneity^2 + RSD_weighing^2 )
```

In a well-homogenized, accurately weighed system, moisture variability becomes the dominant error source if poorly controlled. Pharmaceutical content uniformity standard (USP <905>) allows +/-10%. The moisture contribution alone stays well within this at reasonable targets.

Implication

At a 6% target with 2% SD, moisture contributes ~2% dose RSD. Manageable. At 10% target with poor storage controls (4% SD), it approaches 4.5%. Still within pharmaceutical limits but consuming a large share of the error budget and leaving less room for other variability sources.

---

4. USP <731> Loss on Drying

The pharmacopeial standard method for measuring moisture content in solid biological materials. Simple, cheap, and universally understood by accredited labs.

Procedure

1. Weigh a known mass of sample in a tared glass weighing bottle (analytical balance, +/-0.1 mg)
2. Place in drying oven at 105 C for 2-4 hours
3. Transfer to desiccator, cool to room temperature
4. Re-weigh
5. Calculate: % LOD = ((initial mass - final mass) / initial mass) x 100

Equipment and Cost

Analytical balance (+/-0.1 mg), drying oven (105 C +/- 2 C), desiccator with active desiccant, glass weighing bottles. All standard lab equipment. $20-50 per sample. Any ISO 17025 accredited lab already owns everything needed. Requires only 0.5-1.0 g of flour-grade homogenized powder -- the least material-hungry test in the full panel.

5. Lab Workflow Integration

Split-Sample Methodology (Example)

When a producer submits a sample, the lab splits it into aliquots:

- **Aliquot A** -- LOD oven (0.5-1.0 g): Moisture content of as-received material
- **Aliquot B** -- HPLC (0.5-1.0 g): Potency analysis on as-received material
- **Aliquot C** -- Microbial panel (1-2 g): The material-hungry test
- **Aliquot D** -- Heavy metals ICP-MS (0.3-0.5 g): If required
- **Reserve** -- Remainder held for retest or confirmation

Critical Point

The lab does **not** further dehydrate the potency sample before HPLC. Aliquot B goes into extraction and analysis as-received. The LOD result from Aliquot A is used to calculate and report potency on both an as-received basis and a dry-weight basis.

COA Reporting Structure

A properly structured COA reports:

- Moisture content (% LOD)
- Potency as-received (mg/g at measured moisture)
- Potency dry-weight basis (mg/g corrected to 0% moisture)
- Water activity (a_w) if measured

The dry-weight basis number allows comparison across batches regardless of moisture differences. The as-received number reflects what the patient actually gets.

---

6. Microbial Panel Linkage

Tighter moisture and storage controls reduce the microbial risk profile. Below a_w 0.60, microbial growth stops. Organisms are not killed. Dormant spores survive and mycotoxins are irreversible if present pre-drying. But post-production contamination risk drops to near zero in properly dried and stored material.

If moisture standards are enforced with LOD testing at intake, much of the justification for an extensive microbial panel weakens. The risk analysis shifts from 'what could grow' to 'what was present before drying' -- a pre-harvest/cultivation concern, not a post-production testing concern.

Full microbial panel analysis covered in separate working thread.

References

1. Gotvaldova, K.; Hajkova, K.; Borovicka, J.; Jurok, R.; Cihlarova, P.; Kuchar, M. "Stability of psilocybin and its four analogs in the biomass of the psychotropic mushroom *Psilocybe cubensis*." *Drug Testing and Analysis* 2021, 13(2), 439-446. DOI: 10.1002/dta.2950

2. Gotvaldova, K.; et al. "Extensive Collection of Psychotropic Mushrooms with Determination of Their Tryptamine Alkaloids." *Int. J. Mol. Sci.* 2022, 23(22), 14068.

3. United States Pharmacopeia. USP <731> Loss on Drying. *USP-NF*.

4. United States Pharmacopeia. USP <905> Uniformity of Dosage Units. *USP-NF*.

5. Codex Alimentarius Commission. *Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals* (CAC/RCP 51-2003).

6. FDA. *Water Activity (a_w) in Foods.* 21 CFR Part 117 -- Preventive controls for human food.

Microbiological Panel (Table 1)

Risk Analysis and Cost Assessment

Addendum B to Public Comment | New Mexico Medical Psilocybin Program
NMAC 7.35.2 | Propagation and Testing

Prepared by Gregory Evans | April 23, 2026

Supporting evidence for Items 21, 22, and 23 of the public comment on 7.35.2 NMAC, prepared for the April 24, 2026 hearing.

This addendum presents the biology, pharmacopeial anchoring, regulatory structure, and cost evidence behind those amendments. Recommendation language is settled in the public comment draft.

What the public comment recommends

§19.E Table 1 (routine batch-release testing):

- *E. coli* (generic) at 100 CFU/g
- *Aspergillus flavus*, Present
- *Aspergillus fumigatus*, Present
- *Salmonella* spp., Present

§19.E.1 (compliance-triggered authority): STEC, *C. botulinum*, *P. aeruginosa*, *L. monocytogenes*, *Trichoderma*, *A. niger*, *A. terreus*, TAMC, TYM.

§19.E.2: individual Aspergillus reporting; no collective totals.

New §19 subsection (Item 22): water activity ≤ 0.60.

Pharmacopeial anchors: USP <2023>, <61>, <62>.

Water activity is the preventative control that makes the rest of the framework work.

At $a_w \leq 0.60$, no foodborne pathogen, yeast, or mold relevant to this matrix can grow. The threshold sits below the minimum growth floor of every organism on the current or proposed panel:

- *Salmonella* ≥ 0.94
- *Listeria* ≥ 0.92
- *E. coli* ≥ 0.95
- *C. botulinum* ≥ 0.94
- *A. fumigatus* ≥ 0.85
- *A. flavus* ≥ 0.78 (aflatoxin production requires $a_w > 0.83$)

One inexpensive upstream test validates the environmental condition that every downstream safety claim depends on. [1]

Scope and deference

This addendum is analytical framing on risk proportionality, pharmacopeial anchoring, and regulatory structure. Cost figures are general estimates drawn from published ranges, not quotes. Official pricing, turnaround, method selection, and operational feasibility sit with New Mexico accredited laboratory operators. Costs here cover the microbiological panel only; potency (§19.G), moisture (§19.F), heavy metals, and pesticides are separate testing categories.

Current Table 1 as Proposed by NMDOH

Target Microbe	Action Level
E. coli	100 CFU/gram
A. flavus, A. fumigatus, A. niger, or *A. terreus*	Present
Salmonella spp.	Present
Shiga-toxin producing *E. coli*	Present
Clostridium botulinum	Present
Pseudomonas aeruginosa	Present
Listeria	Present
Trichoderma	Present
Total Yeast and Molds	> 20 CFU

Water Activity, New §19 Subsection

Water activity measures the unbound water available to microbial activity. It is not a measure of total moisture. Two products at the same moisture content by weight can have very different water activity depending on how water is bound in the matrix.

Minimum growth thresholds for organisms on the current or proposed panels:

- *Salmonella* ≈ 0.94
- *Listeria monocytogenes* ≈ 0.92
- *E. coli* ≈ 0.95
- *C. botulinum* ≈ 0.94
- *Aspergillus fumigatus* ≈ 0.85
- *Aspergillus flavus* ≈ 0.78 (aflatoxin production requires a_w > 0.83)

0.60 sits at the food microbiology floor below which no foodborne pathogen is known to grow. [1] Most xerophilic molds are also inhibited at or below this threshold.

What this provides. Water activity converts the microbiological framework from reactive detection to upstream prevention. A batch meeting $a_w \leq 0.60$ cannot develop contamination under its own storage conditions, regardless of downstream handling. Batches exceeding the threshold flag a moisture-control failure before an organism is ever cultured.

Cost. Roughly $15 to $25 per test at laboratories accredited for dried botanicals. Fast turnaround. Compatible with the 30-day release window at §19.

Geographic calibration. New Mexico has among the highest vapor pressure deficit values in the country. Ambient air actively pulls moisture out of hygroscopic material. Dried fungal biomass reaches equilibrium moisture consistent with $a_w \leq 0.60$ without extraordinary controls.

Rule refs: new §19 subsection (Item 22); complements §19.F water content at 10% LOD (Item 21).

Pharmacopeial Anchors

Dried psilocybin mushroom fruiting bodies are a nonsterile, orally ingested, botanical product framed by the Department as pharmaceutical. Three USP standards govern this category:

Standard	Scope	Relevance
USP <2023>	Microbiological Attributes of Nonsterile Nutritional and Dietary Supplements	Product-matrix match for dried botanical supplements. Primary anchor.
USP <61>	Microbial Enumeration Tests for Nonsterile Pharmaceutical Products	Methodology standard for total aerobic and total yeast/mold enumeration.
USP <62>	Tests for Specified Microorganisms in Nonsterile Pharmaceutical Products	Defines route-specific organisms. Scopes *P. aeruginosa* to topical, inhaled, mucosal; *S. aureus* to topical; *C. albicans* to oromucosal.

USP <2023> requirements for botanical supplements:

Test	USP Limit
Total Aerobic Microbial Count (TAMC)	≤ 100,000 CFU/g
Total Combined Yeast and Mold (TYM)	≤ 1,000 CFU/g
E. coli	Absent in 10g
Salmonella	Absent (per USP <2022>)

Four tests. No Aspergillus speciation, no STEC, no *C. botulinum*, no *Pseudomonas*, no *Listeria*, no *Trichoderma*.

How the public comment's Table 1 relates to USP <2023>:

- Covers every USP <2023> organism biologically applicable to this matrix.
- Adds *A. flavus* and *A. fumigatus* speciation beyond USP baseline, reflecting the therapeutic patient population.
- Substitutes water activity ≤ 0.60 for USP TYM enumeration, which is category-incompatible with dried fungal biomass.
- Routes TAMC to §19.E.1 and §20.B. At $a_w \leq 0.60$ bacterial growth cannot occur; the retained pathogen tests cover the bacterial organisms of concern.

Structural Anchors Already in the Rule

Four provisions in the proposed rule already support a narrower routine panel. No new regulatory mechanism is required.

Provision	Authority it already provides
§19.E.1 Compliance-triggered authority	Department may require additional microbial testing when quality control, inspection, or laboratory findings identify a public health concern. Every organism proposed for removal from routine testing remains available here.
§20.B Voluntary labeling	Producers may elect additional testing at their own expense, including "additional pesticides, microbial contaminants, solvents, mycotoxins, and metals." Any producer seeking screened-for status on a removed organism can obtain it without a rule change.
§23 FDA Food Code incorporation	Facility sanitation addresses personal cleanliness, hygienic practices, equipment, water systems, plumbing, and construction. Environmental vectors (*Listeria*, *Pseudomonas*, *Trichoderma*) are handled upstream by facility hygiene, not end-product testing.
§19 30-day release window	All testing must complete within 30 days of homogenization. Tests with turnaround approaching or exceeding this window (notably anaerobic culture for *C. botulinum*) impose a release constraint unrelated to safety.

Aspergillus

Why two species stay routine: Reported individually so the certificate of analysis preserves which species was detected.

A. flavus

- Produces aflatoxins, potent carcinogens and hepatotoxins regulated under WHO and FDA guidance. [2]

A. fumigatus

- Clinically consequential in immunocompromised patients: a population this therapeutic program will include. [3]
- Primary cause of invasive aspergillosis

Triggered testing: *A. niger* and *A. terreus*

- Opportunistic agents documented almost exclusively in severely immunosuppressed individuals (dialysis, transplant, hematologic malignancy)
- Neither is required by USP <2023>
- Collective reporting of all four under §19.E.2 as proposed dilutes the diagnostic signal from the two species that drive patient risk

Panel: Routing, Biology, and Cost

Per-organism routing, matrix-specific biology, and cost tier. Full biological reasoning for each line item is presented in Addendum C.

Cost tiers: Low: ~$15-50 | Moderate: ~$50-100 | High: $150+

Actual pricing varies by laboratory, method, and bundling.

Organism / test	Recommendation	Cost	Core rationale
E. coli (generic)	**Routine, 100 CFU/g**	Low	Fecal hygiene indicator; biological surrogate for STEC. USP <2023> baseline.
A. flavus	**Routine, Present, individual**	Mod. (bundled)	Aflatoxin producer. The only Aspergillus with documented mycotoxin risk in stored agricultural products.
A. fumigatus	**Routine, Present, individual**	Mod. (bundled)	Primary cause of invasive aspergillosis. Relevant to immunocompromised patient population.
Salmonella spp.	**Routine, Present**	Low	High severity if detected; low per-test cost. USP <2023> baseline.
Water activity	**New §19, $a_w \leq 0.60$**	Low	Upstream preventative control below microbiological growth floor.
A. niger / A. terreus	**§19.E.1 triggered**	Bundled	Opportunistic in severely immunocompromised only. Not required by USP.
STEC	**§19.E.1 triggered**	Mod.	Pathogenic subset of *E. coli*, same vector. Not in USP <2023>, <61>, or <62>. [4]
C. botulinum	**§19.E.1 triggered**	High	Requires anaerobic conditions and $a_w > 0.94$. Dried product at $a_w \leq 0.60$ cannot support it. [5]
P. aeruginosa	**§19.E.1 triggered**	Low-Mod.	USP <62> scope: topical, inhaled, mucosal. Not an oral-route organism.
L. monocytogenes	**§19.E.1 triggered**	Mod.	Cold-chain RTE organism. Min. growth $a_w \sim 0.92$. Not in USP <2023>.
Trichoderma	**§19.E.1 triggered**	Low-Mod.	Not listed as human pathogen in any pharmacopeial or food-safety standard. Cultivation indicator.
TAMC / TYM	**§19.E.1 triggered**	Low	Category-incompatible with dried fungal biomass. No valid threshold for this matrix.

Cost Sanity Check

Specific dollar figures depend on laboratory, method, sample volume, and whether retest requirements consolidate tests. The framing below is directional.

Proposed routine panel, per release test

- *E. coli*: Low
- *A. flavus* and *A. fumigatus* (bundled speciation): Moderate
- *Salmonella*: Low
- Water activity: Low

Four Low-tier tests plus one Moderate-tier bundle. Aggregate cost lands in roughly the **$120 to $210 range** per release event, depending on lab and bundling.

Current Table 1 as proposed, per release test

Everything above, plus:

- STEC: Moderate
- *C. botulinum*: **High.** Anaerobic culture is the single most expensive item on the panel.
- *Pseudomonas*: Low to Moderate
- *Listeria*: Moderate
- *Trichoderma*: Low to Moderate
- TYM: Low

Aggregate cost lands in roughly the **$420 to $800+ range**. *C. botulinum* alone can add $150 or more and is the primary driver of the high end.

Order-of-magnitude delta

The proposed narrower panel runs roughly a third to half the cost of the current panel per release test. The largest single saving comes from routing *C. botulinum* to triggered testing where it belongs.

Annualized

Retest cadence is a matter for Department judgment and is not addressed in this addendum. Whatever cadence the Department adopts, the per-event delta between the proposed and current panels compounds across every release and retest without any reduction in patient safety.

These estimates come from published laboratory pricing ranges for comparable tests in cannabis, dietary supplement, and pharmaceutical QC markets. The Department should validate final pricing with New Mexico accredited laboratory operators before setting policy.

Compliance-Triggered Testing Framework

Trigger conditions connecting each organism routed out of the routine panel to a specific risk scenario, so the Department's existing authority at §19.E.1 can be exercised with clear cause.

Organism	Trigger condition	Rationale
STEC	Substrate pasteurization failure; water system contamination event; positive *E. coli* result at routine testing.	Pathogenic subset of *E. coli* sharing the same transmission vector. Triggered when surrogate indicator flags the contamination class or upstream controls fail.
C. botulinum	Authorization of non-dried product form (oil infusion, vacuum-sealed moist product, fermented preparation); a_w exceedance above 0.94 at inspection.	Anaerobic germination conditions cannot exist in dried product at $a_w \leq 0.60$. Triggered only when conditions that enable the organism become possible.
P. aeruginosa	Water system failure; storage non-compliance; elevated moisture at inspection; authorization of topical, inhaled, or mucosal product form.	Water-associated organism relevant when moisture controls break down or route of exposure shifts to topical, mucosal, or inhaled (USP <62> scope).
Trichoderma	Facility process audit identifies recurring *Trichoderma* presence in cultivation environment; substrate quality concerns.	Cultivation process indicator, not product safety indicator. Belongs in facility inspection, not batch-release testing.
L. monocytogenes	Post-harvest handling contamination event; patient-population epidemiological concern; facility inspection findings.	Minimum growth $a_w \sim 0.92$, precluded at $a_w \leq 0.60$. Triggered under specific environmental or clinical cause.
A. niger / A. terreus	Elevated water activity at inspection; storage condition violations; patient-population immunocompromise concern.	Lower clinical significance than *A. flavus* and *A. fumigatus*. Routine speciation for the two retained species is sufficient.
TAMC / TYM	Department quality-assurance initiative; broad-spectrum contamination suspicion.	Neither test yields actionable signal on this product matrix at $a_w \leq 0.60$. Available if Department identifies cause.

Authority preserved in full. Routine testing aligned with the actual consumer-safety risk profile in this matrix.

References

Cited in this addendum

[1] FDA. *Water Activity in Foods*, Inspection Technical Guide.
https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-technical-guides/water-activity-aw-foods

[2] WHO. *Mycotoxins Fact Sheet.*
https://www.who.int/news-room/fact-sheets/detail/mycotoxins

[3] Aspergillus pathogenicity review. *PMC* 2021.
https://pmc.ncbi.nlm.nih.gov/articles/PMC8363598/

[4] CDC. Shiga Toxin-Producing *E. coli*.
https://www.cdc.gov/e-coli/about/index.html

[5] FDA Bad Bug Book. *Clostridium botulinum.*
https://www.fda.gov/food/foodborne-pathogens/clostridium-botulinum

[6] USP <2023>. Microbiological Attributes of Nonsterile Nutritional and Dietary Supplements.
http://uspbpep.com/usp29/v29240/usp29nf24s0_c2023.html

[7] Ludewig et al. 2024. Microbiological quality of dried mushrooms. *MDPI Applied Sciences* 14(5), 2208.
https://www.mdpi.com/2076-3417/14/5/2208

Existing regulated program comparators

Colorado (CO) testing panel requirements
https://knowing-flight-1ea.notion.site/colorado-co-testing-panel-requirements

Oregon (OR) testing panel requirements
https://knowing-flight-1ea.notion.site/oregon-or-testing-panel-requirements

Additional references

USP standards

USP <2023> Full Tables (PDF): https://www.drugfuture.com/Pharmacopoeia/usp35/PDF/0962-0965%20%5B2023%5D%20MICROBIOLOGICAL%20ATTRIBUTES%20OF%20NONSTERILE%20NUTRITIONAL%20AND%20DIETARY%20SUPPLEMENTS.pdf

Operating state psilocybin programs

1 CCR 213-1, Part 4 (Colorado Regulated Natural Medicine)

OAR 333-333-7010 through 7100 (Oregon Psilocybin Services)

Cannabis state regulations

Medicinal Genomics, state-by-state cannabis microbial testing: https://medicinalgenomics.com/resource/cannabis-microbial-testing-regulations-by-state/

NM medical cannabis (7.34.4 NMAC): https://www.law.cornell.edu/regulations/new-mexico/N-M-Admin-Code-SS-7.34.4.10

CO cannabis contaminant testing (1 CCR 212-3): https://www.law.cornell.edu/regulations/colorado/1-CCR-212-3-4-215

CA water activity for cannabis flower (4 CCR 15717): https://www.law.cornell.edu/regulations/california/4-CCR-15717

PMC, State Cannabis Contaminant Regulations comparison, 2022: https://pmc.ncbi.nlm.nih.gov/articles/PMC9472674/

Dried mushroom studies

Ludewig et al. 2024: https://www.mdpi.com/2076-3417/14/5/2208

EFSA/Czech *B. cereus* study (Sykorova et al.): https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/fr.efsa.2026.FR-0090

Pathogen survival during drying: https://www.sciencedirect.com/science/article/pii/S0956713521008537

Aspergillus and mycotoxins

WHO Mycotoxins Fact Sheet: https://www.who.int/news-room/fact-sheets/detail/mycotoxins

FDA Mycotoxins Overview: https://www.fda.gov/food/natural-toxins-food/mycotoxins

Aspergillus on dried mushrooms, Nigeria, 2013: https://pubmed.ncbi.nlm.nih.gov/23454813/

Advanced Science, Aspergillus mycotoxin review, 2025: https://advanced.onlinelibrary.wiley.com/doi/10.1002/advs.202412757

Pathogen references

CDC Botulism: https://www.cdc.gov/botulism/about/index.html

CDC STEC: https://www.cdc.gov/e-coli/about/index.html

FDA, *Salmonella* Stanley / dried wood ear outbreak, 2020:
https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-salmonella-stanley-wood-ear-mushrooms-dried-fungus-september-2020

NACMCF RTE Testing Guidance (PDF): https://www.fsis.usda.gov/sites/default/files/media_file/2022-03/NACMCF_2018-2020_RTE_Testing.pdf

Water activity

Anresco, Moisture and water activity explained: https://anresco.com/cannabis-rd/moisture-water-activity/

Eurofins, Microbiological specifications in food operations: https://www.eurofinsus.com/food-testing/resources/microbiological-specifications-in-food-operations/

Panel Breakdown, Per-Organism Analysis

Addendum C to Public Comment | New Mexico Medical Psilocybin Program
NMAC 7.35.2 | Propagation and Testing

Prepared by Gregory Evans | April 23, 2026

Target-by-target analysis supporting §19.E Items 22 and 23 of the public comment on 7.35.2 NMAC. Each entry evaluates one organism against the product matrix, pharmacopeial standards, and the §19 release window. Companion to Addendum B. Method selection and validated SOPs remain with accredited laboratories.

1. *E. coli*, 100 CFU/g

Routing: Routine, §19.E Table 1, 100 CFU/g

Standard fecal hygiene indicator across food and pharmaceutical frameworks. USP <2023> requires *E. coli* absent in 10g for nonsterile botanical supplements. The rule's 100 CFU/g is a quantitative action level, less stringent than the USP absence standard. Consistent with cannabis regulatory practice. Generic *E. coli* also serves as the biological surrogate for STEC (Section 4): same fecal transmission vector, same upstream controls. Minimum growth $a_w \approx 0.95$, precluded at $a_w \leq 0.60$.

2. *Aspergillus*, Present (individual species)

Routing: Routine — A. flavus and A. fumigatus, Present, reported individually (§19.E.2)

Routing: §19.E.1 triggered — A. niger and A. terreus

A. flavus produces aflatoxins, potent carcinogens and hepatotoxins regulated under WHO and FDA guidance. *A. fumigatus* is the primary cause of invasive aspergillosis and is clinically consequential in immunocompromised patients, a population this therapeutic program will include. Both warrant routine batch-release screening.

A. niger and *A. terreus* are opportunistic agents documented almost exclusively in severely immunosuppressed individuals (dialysis, transplant, hematologic malignancy). Neither is required by USP <2023>. Their inclusion on routine, paired with collective reporting, dilutes the diagnostic signal from the two species that actually drive patient risk.

Reporting matters. The current §19.E.2 permits laboratories to report the four *Aspergillus* species collectively. Under collective reporting an *A. flavus* detection (serious aflatoxin concern, batch-reject) is indistinguishable on a certificate of analysis from an *A. niger* detection (negligible risk in this matrix). Amending §19.E.2 to require individual-species reporting preserves the diagnostic value the test exists to produce.

Action level. Presence-based reporting is appropriate given the therapeutic context. Aflatoxin exposure and invasive aspergillosis in a medical product do not tolerate a quantitative threshold argument. Water activity ≤ 0.60 precludes post-release growth of any *Aspergillus* species.

3. *Salmonella* spp., Present

Routing: Routine, §19.E Table 1, action level Present

USP <2023> baseline for botanical supplements and USP <62> baseline for oral-route nonsterile pharmaceuticals. High severity if detected, low per-test cost, biologically plausible under contamination scenarios that matter. Transmission requires animal-origin fecal contamination; facility separation from livestock, an operational standard, removes the vector upstream of testing. Minimum growth $a_w \approx 0.94$, precluded at $a_w \leq 0.60$.

Only one documented outbreak in dried mushrooms (imported wood ear, FDA 2020), involving an uncontrolled import supply chain distinct from indoor cultivation under this rule.

4. Shiga-toxin producing *E. coli* (STEC), Present

Routing: §19.E.1 triggered. Redundant with generic E. coli on routine.

STEC is a pathogenic subset of *E. coli* defined by *stx1*/*stx2* toxin genes. It shares the exact fecal transmission vector as generic *E. coli*. When generic *E. coli* is absent in the sample, STEC is necessarily absent. Separate STEC testing duplicates the same contamination class rather than adding an independent safety layer.

Food-source STEC contamination is almost exclusively linked to cattle and ruminants (ground beef, raw dairy, manure-runoff produce). No plausible pathway exists in indoor-cultivated dried mushroom product. Manure-based substrates, where used, undergo composting, aging, drying, and thermal pasteurization before cultivation contact, as locked by the Propagation Committee's adopted framework.

Not listed in USP <2023>, <61>, or <62>. Available under §19.E.1 if substrate pasteurization fails, water system contamination is observed, or positive generic *E. coli* at routine flags the contamination class.

5. *Clostridium botulinum*, Present

Routing: §19.E.1 triggered

C. botulinum requires strict anaerobic conditions and $a_w > 0.94$ to germinate and produce toxin. Dried product at $a_w \leq 0.60$ is the opposite of every required condition: aerobic and well below the growth floor. Spores are environmentally ubiquitous but do not germinate or produce toxin in dried, aerobic matrices. Botulism risk lives in improperly canned foods, vacuum-sealed moist products, oil infusions, and fermented products, none of which are authorized under §11 (Allowed Psilocybin Products).

Not listed in USP <2023>, <61>, or <62>. Not required by any cannabis or psilocybin regulatory program. No documented botulism case linked to dried mushrooms of any kind.

Anaerobic culture is also the single most expensive test on the panel and its turnaround strains the §19 30-day release window without a corresponding safety benefit. Available under §19.E.1 if a non-dried product form is authorized or if $a_w > 0.94$ is observed at inspection.

6. *Pseudomonas aeruginosa*, Present

Routing: §19.E.1 triggered. Misapplied standard on current panel.

USP <62> lists *P. aeruginosa*, but scopes it specifically to **topical, inhaled, and mucosal** products: wound care, eye drops, nasal sprays, vaginal products. The standard does not apply to orally ingested products. USP <2023> does not list it for botanical supplements. Applying a route-specific standard to the wrong route is a category error.

Minimum growth $a_w \approx 0.97$, precluded at 0.60 by a wide margin. Desiccation during drying further reduces viability. Oral ingestion is not a recognized foodborne illness pathway for this organism in immunocompetent patients. The clinical significance (wound infection, respiratory colonization) requires exposure routes that do not exist for this product.

Available under §19.E.1 on water system failure, storage non-compliance, elevated moisture at inspection, or authorization of a topical, inhaled, or mucosal product form.

7. *Listeria*, Present

Routing: §19.E.1 triggered

L. monocytogenes is dangerous because it grows at refrigeration temperatures, which is what makes it a risk in cold-chain ready-to-eat foods (deli meats, soft cheeses, smoked fish, fresh produce). It is not a shelf-stable dried botanical organism. Minimum growth $a_w \approx 0.92$, precluded at $a_w \leq 0.60$. No documented listeriosis outbreaks linked to dried mushroom products.

Not required by USP <2023> for botanicals. Required by USDA/FDA for refrigerated RTE products, not for shelf-stable dried botanicals.

Available under §19.E.1 on post-harvest handling contamination, patient-population epidemiological concern, or inspection findings.

8. *Trichoderma*, Present

Routing: §19.E.1 triggered. Ghost test on a homogenized product.

Not a human pathogen. Not classified as foodborne by any regulatory body worldwide. Produces no toxins relevant to oral exposure. EPA registers *T. harzianum* as a beneficial biocontrol agent sold commercially for agricultural disease suppression.

Invasive *Trichoderma* infections exist in the medical literature but exclusively in severely immunocompromised patients (dialysis, transplant, hematologic malignancy), almost always from environmental or respiratory exposure rather than ingestion. Global case count: low dozens over decades.

Homogenized-product problem. On powder, *Trichoderma* detection functions as a cultivation process quality indicator, not a product safety indicator. It says "the grow was contaminated," not "the consumer is at risk." Detection on homogenized product cannot be traced to origin, linked to a specific process failure, or connected to a consumer safety outcome. Water activity ≤ 0.60 precludes active growth regardless of historical load.

Not in any standard. Not listed in USP <2023>, <61>, or <62>; not in FDA foodborne guidance; not in the European Pharmacopoeia; not in any U.S. cannabis program. Cultivation *Trichoderma* concerns are better handled upstream under §23 (Producer Requirements for Sanitation and Product Handling, incorporating the 2022 FDA Food Code) and through on-site department monitoring under §25 (Monitoring and Corrective Actions), with §19.E.1 available if an inspection or audit identifies cause.

9. Total Yeast and Molds (TYM), > 20 CFU

Routing: Remove from Table 1. Available under §19.E.1.

TYM measures fungi. The product is dried fungal biomass. The test is category-incompatible with the matrix. Any TYM count on dried mushroom product captures spores from the target organism itself alongside environmental fungi and substrate organisms. Achieving ≤ 20 CFU would require near-pharmaceutical-grade cleanroom processing or terminal sterilization. No meaningful interpretation is available.

The threshold has no apparent basis. The proposed > 20 CFU action level (unit unspecified, presumably per gram) does not correspond to any recognized standard:

Standard	Limit
USP <2021> nonsterile pharma	100 to 1,000 CFU/g
Colorado cannabis flower	< 10,000 CFU/g
Ludewig 2024 retail dried mushrooms (n=61)	~30 to 40 CFU/g, deemed acceptable

At 20 CFU/g the threshold is roughly 500x more stringent than NM's own medical cannabis program and would fail dried mushroom samples that peer-reviewed research deemed acceptable.

No threshold fix resolves the incompatibility. The issue is the test itself on this matrix, not the number. Water activity ≤ 0.60 physically precludes active fungal growth post-release, which is the outcome a TYM limit is intended to protect. TAMC is similarly inappropriate for routine: at $a_w \leq 0.60$ bacterial growth cannot occur, and the retained specific pathogen tests cover the bacterial organisms of concern. Both TYM and TAMC remain available under §19.E.1.

References for every organism above are consolidated under References in Addendum B.