EXHIBIT 8

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

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[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.