Via E-Mail

May 13, 2026

Craig Erickson
Utton & Kery, P.A.
500 Tijeras Ave. NW
Albuquerque, NM 87102
E-mail: craig@uttonkery.com

Re: Public Comments in Rulemaking for 7.35.2 NMAC, Medical Psilocybin; Producer and Laboratory Requirements

Dear Mr. Erickson:

The New Mexico Department of Health offers the following responses to substantive proposals made in the public comments submitted during the rulemaking proceeding for the proposed new rule 7.35.2 NMAC, Medical Psilocybin; Producer and Laboratory Requirements.

A. Written Public Comments of Mr. Gregory Evans

Mr. Gregory Evans is a researcher and a member of the Medical Psilocybin Advisory Board's Propagation Committee, who offered several proposed edits to the rule. Of the changes requested by Mr. Evans, the Department proposes to adopt the following:

1. Definition of Certificate of Analysis (p. 6, Item 10): The Department agrees that a definition of "certificate of analysis" should be added in 7.35.2.7 NMAC. However, the Department prefers the following abbreviated text: "Certificate of analysis or COA means a document issued by a permitted psilocybin testing laboratory that reports the results of all analyses required by the department or additional testing requested by a producer or manufacturer."

2. Maximum Water Content of 10% (p. 7, Item 21): Mr. Evans proposed adding a 10% maximum water content requirement. The Department agrees, and included this proposed edit in its List of Anticipated Revisions to the proposed rule, announced by Dr. Dominick Zurlo at the hearing on April 24, 2026.

3. UID Assignment - Omits Cultivation Batch (p. 10, Item 27): Section 7.35.2.10(A)(6) omits the term cultivation batch from unique identification number (UIN) assignment. Although the term cultivation batch appears in other references in the rule for assignment of UIN, the Department suggests adding the terms "cultivation batch" to the language in 7.35.2.10 AA6.

4. UID Assignment-Omits Harvest Lot (p. 10, Item 28): The requested addition of "harvest lot" to section 7.35.2.15(A)(1) NMAC was made prior to the rule hearing.

With respect to the other comments of Mr. Gregory Evans, the Department responds as follows:

5. Add Definition for "Inoculate" (p. 1, Item 1): The Department understands that spores do not contain psilocybin. "Psilocybin spore" refers to a spore that produces a mushroom containing psilocybin. The Departments does not believe that adding the term "inoculate" would be beneficial.

6. "Psilocybin" - Bundled Compound Creates Regulatory Ambiguity (p. 1, Item 2): The rule definition of "psilocybin" is identical to the statutory definition at section 26-2D-3(G), NMSA 1978. The definition should not be altered.

7. "Cultivation" and "Manufacture" - Overlapping Scope (p. 2, Item 3): The Department believes that the language of the proposed text is clear and does not lead to "conflicting obligations", nor prevent the assignment of unique identification numbers for each stage.

8. "Potency" - Required Analytes Unspecified (p. 2, Item 4): Potency testing and required analytes are specified later in the rule at section 7.35.2.19(G) NMAC. The rule sets the reporting measurement in milligrams/gm, which is a metric unit.

9. "Mycelium" - Unnecessary Species Qualifier (p. 3, Item 5): The Department believes that the definition of "mycelium" is sufficiently accurately for the program's purposes. If a cultivation batch is contaminated with Trichoderma, aspergillus or other fungal contaminants that have mycelium, the Department may reference the species by name.

10. "Fruiting Bodies" - Reduced to Single Function (p. 3, Item 6): The Department believes that the definition of "fruiting bodies" is sufficiently accurately for the program's purposes. Adding the words "including associated structures" might be technically more specific, but would not add clarity or needed meaning to the definition.

11. Lot Hierarchy - Definitions Do Not Enforce the Intended Chain (p. 3, Item 7): To accurately track growing, harvesting, and producing the psilocybin-containing mushrooms for use, growth stages needed to be defined in the rule to allow for tracking and to prevent diversion.

a. Chain Broken: The Department believes that the definitions are accurate, and that they can be followed by producers without confusion. Adding "parent stages" would not add additional meaning to the rule.

b. Mixed genetic heritage: This was intentional to allow producers to grow multiple species of psilocybin-containing mushrooms that may vary in psilocybin content. Testing of the finished product will determine the important parameter of amount of psilocybin contained in the product.

c. Homogenization: Adding the word "powdered" to the definition of homogenized lot, when the definition of homogenized requires "powdering", would be redundant and unnecessary.

d. Product Lot: The Department is satisfied with the current definition and believes that the proposed longer and more complex definition would not reduce confusion or add meaningful information.

e. UID: The Department concurs with the proposal to add "cultivation batch" to 7.35.2.10(A)(6) NMAC (see above).

f. Dead Clause: The lack of a time value assigned to the phrase "Harvested within a specified time period" was intentional, to allow for the producer to self-determine the time period, based on business practice and different growth time for different types of psilocybin-containing mushrooms.

12. Unique Identification Number - Permissive Scope (p. 4, Item 8): The Department believes that the words "may include" do not grant permission to ignore assigning a unique identification number to each stage as defined.

13. "Spawn" - Recommended Addition (p. 5, Item 9): The Department believes that adding a definition for the word "spawn" would not add meaningful content to the rule. Spawn arise from germinating spores and are not a separate biological entity.

14. "Shelf Life" - Recommended Addition; "Stability" - Recommended Addition (p. 5, Items 11 and 12): The Department has not defined a shelf life or expiration date for psilocybin product as there is little scientific information regarding the stability of homogenized powdered psilocybin mushrooms. A single study was identified by the Department, entitled "Stability of psilocybin and its four analogs in the biomass of the psychotropic mushroom Psilocybe cubensis", by Gotvaldova, Hajkova et al. This study found some degradation of psilocybin beginning at 1 month even under the best storage conditions and a more pronounced drop between 2 and 15 months. An additional study from Rose City Labs found conversion of psilocybin to psilocin with a small decrease in potency after 3 months of storage.

Because of the lack of substantial data on stability for stored powdered psilocybin, the Department opted in favor of requiring re-testing every six months, to balance safety, potential decreasing potency requiring change in dosing amount, and testing costs. As the Department gains experience with the results of testing, the rules allow for changing testing frequency as needed.

15. Definitions to Defer (p. 6, Items 13-20): The Department has proposed adopting certain definitions in the Psilocybin Producer and Laboratory Requirements rule that are particular to psilocybin patients and practitioners. Some of these are not used at all outside of definitions. The Department has proposed these definitions in anticipation that the definitions used in this rule will be incorporated in their entirety by reference in future rules concerning patients and practitioners. If those definitions are determined to require revisions in the future, they can be amended at that time.

16. New Subsection - Water Activity (New Provision) (p. 7, Item 22): The Department believes adding a subsection regarding water activity would be redundant and unnecessary, as a water content of 10% is generally analogous to a water activity of the proposed 0.6 aw in the public comment. Although a water activity measurement of 0.6 aw or less could in theory inhibit the growth of bacterial/yeast and mold in the finished product, this alone would not guarantee that the product is not contaminated. This is part of why the Department has proposed to require additional testing for contaminants.

17. Microbiological Panel - Scope, TYM, and Aspergillus Reporting (p. 8, Item 23): The Department believes that testing for each of the required microbiological species is reasonable and

appropriate. The medical conditions that qualify a patient for enrollment in in the New Mexico Medical Psilocybin Program often come with comorbidities, including immunosuppression, which require pathogen-free mushroom products. Each required species to be tested can cause serious illness or death in patients who are immunocompromised or seriously ill. The testing panel was created after consultation with the American Herbal Products Association (AHPA), the USDA, the National Advisory Committee on Microbiological Criteria in Foods (NACMCF), review of Oregon and Colorado Psilocybin program requirements and discussion with psilocybin testing labs in Colorado, Oregon and Florida. The Department is also concerned that the Psilocybin Program may attract novice producer entrants with varying skill levels. The Department finds that more thorough testing at the start will better ensure the safety of patients. As the Department gains experience with the testing results of testing, the testing frequency can be adjusted through future rulemaking as needed.

18. Retest Cadence (p. 8, Item 24): The Department believes that referencing the re-test cadence in four passages of Section 19 of the rule is not problematic, and serves a useful purpose, as each reference pertains to the testing of different analytes.

19. Sample Size - Fixed Range Conflicts with Laboratory Requirements (p. 9, Item 25): Having consulted with laboratories in Colorado and Oregon, the Department believes that a sample size of 1-5 grams will be sufficient for all testing, and gives producers notice of the amount of product that they can expect to lose in the course of testing. These amounts should be in line with laboratory standard operating procedures.

20. Residual Solvents - References Not Applicable to Authorized Product Forms (p. 9, Item 26): While the proposed rule does not authorize solvent-based extraction, the Department anticipates that solvents could be used for cleaning and disinfection, and that solvents could therefore contaminate mushroom products. Additionally, the Department believes it is important to require the wastage of products that are manufactured using solvents, all of which would be deemed unapproved at this time. The Department does not believe that modifying these references in the rule would be beneficial.

21. Potency Calculation - "Total Psilocybin Equivalent" and "Total Potential Psilocin" Undefined (p. 10, Item 29): The Department believes that it is unnecessary to include conversion factors, analyte inputs, and calculation formula in the rule, as these parameters have been standardized via accepted standardized operating procedures for testing laboratories.

B. <u>Written Public Comments of Mr. James Brown</u>

1. Recall Classifications: Mr. James Brown proposed that the Department incorporate various additional text in the rule to require three classes of recalls, ranging from Class 1 to Class 3. The Department believes that the proposed text, at Sections 7.35.2.10 (A)(8) and 7.35.2.19 (M)(1) through (5) NMAC, is sufficient, and gives clear, simple instructions on the recall procedure, as well as the destruction of any psilocybin lot that poses a health hazard or that fails a visual inspection or laboratory test. The Department is concerned that the proposed text would unnecessarily complicate the recall process.

2. Various Definitions: Mr. Brown recommended that the Department adopt definitions for various expressions and utilize them in the rule, including definitions for "referring clinician", "determining clinician", "guides or facilitators", and "integration provider". The Dosage, Administration & Clinical Practice (DACP) Committee and the Training & Education Committee of the Medical Psilocybin Advisory Board are currently working together to make recommendations concerning licensures and the qualifications, competencies, scope of practice, and roles for each. The Department anticipates addressing these matters in future rulemaking.

3. Dual Ownership Prohibited: Mr. Brown recommended that the prohibition against dual ownership by a permittee be modified to allow a person holding either a producer or laboratory permit to hold an interest in another permittee, so long as there was clear separation between the operations of each permittee. The Department believes that allowing persons who have ownership interests in a permittee to hold ownership interests in other permittees can raise various conflicts of interest that would ultimately be detrimental to patients in the Medical Psilocybin Program. One of the biggest conflicts poses is the potential for market monopoly: if a person holds an ownership interest in multiple entities, they could use their position to favor their own products. In the case of dual ownership in a producer and a laboratory, the conflict is even more stark, as those persons would be incentivized to skew or falsify test results.

C. Written Public Comments of Mr. Jonathan M. Dennis

Mr. Jonathan M. Dennis offered public comments on behalf of the Psychedelic Bar Association.

1. Intersections of Medical and Religious Use: Mr. Dennis stated that regulations should acknowledge religious use and the right of religious adherents to legally access psilocybin. As Mr. Dennis correctly noted, the Medical Psilocybin Act makes no reference to religious use. The Act does not authorize the NM Department of Health to enroll individuals in the NM Medical Psilocybin Program for religious use of psilocybin. While the Department understands that religious use may be deemed lawful, consistent with the terms of the United States and New Mexico Constitutions and applicable case precedents interpreting the same, it is not within the legal role of this agency to enroll persons for religious use of psilocybin. The Medical Psilocybin Program is a medical program, and discussion of religious use of psilocybin is beyond the scope of the program and the proposed rule.

2. Sale Restrictions and Federal Tax Consequences (pp. 4-6): Mr. Dennis expressed concern that transfers of psilocybin from producers to service centers would trigger exposure for the service center under Section 280(E) of the Internal Revenue Code, which prohibits businesses engaged in the trafficking of a Schedule I controlled substance from deducting ordinary business expenses from their federal taxes. Mr. Dennis recommended allowing direct sales from producers to patients to reduce the impact of Section 280(E).

Allowing direct sales of psilocybin from producers to patients would encourage self-dosing and recreational use. Irrespective of potential tax implications, the Department is committed to ensuring that producers of medical psilocybin products only distribute those products to clinicians, and that the administration of medical psilocybin only occurs in supervised clinical settings.

Psilocybin presents unique health risks and is in that regard very different from medical cannabis. In adopting the Medical Psilocybin Act, NMSA 1978, §§ 26-2D-1 through -11, the NM Legislature emphasized the involvement of clinicians and the ingestion of psilocybin only in supervised administration sessions as part of an integrated therapeutic practice. The Department's approach is consistent with that expressed legislative intent.

3. Anticipating and Reducing Negative Consequences of Profit Motives (pp. 6-7):
in the State Program: Mr. Dennis highlighted the proposed requirement that permittee investors "enjoy the customary incidents of ownership". Mr. Dennis recommended that the rule clarify that passive investments are allowed within the program. The Department believes that the proposed text, particularly as revised in response to public comments (described in the List of Anticipated Revisions to the proposed rule discussed at the rule hearing) is appropriate. Requiring that investors enjoy the customary incidents of ownership proportionate to their percentage ownership is not unduly burdensome, and will help to ensure that permittees do not enter "straw man"-type arrangements whereby actual control of a company is vested in persons other than those who hold record ownership of the business, etc.

4. Restrictors for Property-Renting Applicants: Mr. Dennis proposed that the rule not require that a permit applicant submit an attestation from a landlord acknowledging that their property will be used to cultivate psilocybin on the premises. Mr. Dennis expressed concern that such an attestation could expose a landlord to potential civil and criminal liability, and that landlords would be reluctant to provide an attestation. He stated that there should be a "lease agreement pathway", and that the scope of any written approval should be limited to only requiring permission to participate in a DOH-licensed program.

The Department believes it is important for permit applicants and permittees to provide an attestation from a landlord acknowledging that they understand how the premises will be used, particularly given the state of federal law and the potential for negative legal repercussions for landlords (such as property seizures, etc.), including those land owners who may not be aware of the activities occurring on the leased premises. However, in response to the public comments on this subject, the Department proposes to modify the proposed text at section 7.35.2.8(A) NMAC 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 the tenant will be participating in the medical psilocybin program as a permittee and what their permit allows;

D. Written Public Comments of John Starr

Mr. Starr stated that the rules should be written in a manner that favors small business, and expressed concern that the proposed rule does not encourage investment and could restrict access

to medical psilocybin by making it too expensive. The Department believes that the proposed rule strikes an appropriate balance between ensuring the safety of psilocybin products and avoiding the imposition of unnecessary expenses and restraints.

E. Written Public Comments of Denali Wilson, Esq. and Victoria J. Cvitanovic, Esq.:

Ms. Denali Wilson and Ms. Victoria J. Cvitanovic offered extensive public comments, including several proposed amendments, on behalf of the Healing Advocacy Fund and the Rudick Law Group.

1. Gaps in Protections Against Predatory Financing and Disguised Control

Ms. Wilson and Ms. Cvitanovic proposed various amendments to limit the potential for predatory financing and strawman-type arrangements within the Program, which included proposed edits to the definition of "actual control" and the proposed deletion of the definition of "genuine ownership". In consideration of this comment, the Department proposed certain edits to the rule, which were included in the List of Anticipated Revisions announced by Dr. Zurlo at the hearing on April 24, 2026. The Department proposed to revise the definition of "actual control" as follows:

> **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.

Pursuant to section 7.35.2.9(D) NMAC, transfer of actual control of an applicant or permittee would be prohibited. By the above edits to the definition of "actual control", whether someone has "actual control" over a permittee depends on whether they can dictate the policies, priorities, etc. of the permittee, and not whether they can "exert authority" over the permittee. The revised text would enable someone who has an ownership interest in a permittee to vote their shares, exerting an influence on the business' operations without having absolute control over the business. These edits are also consistent with 7.35.2.9(E) NMAC, which would 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".

The Department believes that the text of the proposed rule, as revised, is relatively straightforward and adequately addresses the subject of ownership interests in a permittee. In contrast, The Department believes that the proposed text, which include lengthy revisions to the definition of "actual control" and multiple passages regarding new "true parties in interest" designation, would be overly complicated and would not add significant value. Again, the proposed text (as revised) allows for investment in permittees, and generally allows persons with ownership interests to exert control on the business (vote their shares, etc.), provided that *outright control* over the business cannot be transferred, except in the limited circumstance (described in the List of Anticipated Revisions discussed at the rule hearing) in which a sole proprietor dies and the Department has authorized the transfer of the permit.

2. Clarity Regarding Rules Into Investment Into Permitted Businesses

The comment included various proposed edits to section 7.35.2.2 NMAC, "General Permittee Requirements". Here again, the Department believes that the proposed edits would overly complicate the rule, without adding significant value. The rule at 7.35.2.9(B) NMAC would prohibit a person who holds an ownership interest in a permittee from holding an ownership interest in another permittee. The Department believes that this is necessary to prevent conflicts of interest and negative impacts on the Program that can result. The comment's proposed text attempts to differentiate between ownership interests and control, and would permit dual ownership so long as the person doesn't qualify as a "true party in interest" (i.e., a person who hold actual control) with respect to the second permittee. The Department believes that prohibiting dual ownership is a more robust and practical approach to limiting the potential for predatory financing and disguised control of permittees. Prohibiting dual ownership, and requiring record ownership, will provide bright-line standards that are both simpler for the Department to enforce and easier for regulated entities to follow. Shifting entirely to a control-based approach would be difficult to implement, as it would be difficult to distinguish between persons who are simply passive investors and persons who exert control over a permittee through backroom decision-making. Prohibiting dual ownership will help to preserve market competition and diversity, in part by limiting the potential for de facto monopolies and promoting small businesses. The desire to generate more lending opportunities within the industry, though laudable, does not outweigh these compelling interests.

Again, the proposed rule (as revised) allows the transfer of ownership interests in a permittee; it only prohibits the transfer of outright control of a permittee to another person, except in the circumstance involving the death of a sole proprietor. The proposed rule does not compel investors in a permittee to "take responsibility for compliance and actions of the permittee": it only requires that an ownership interest in a permit not be nominal or without the benefits and risks of genuine ownership or control, which is defined to mean that the persons enjoys the customary incidents of ownership and shares in the profits and losses of the permittee proportionate to the percentage of their ownership interest. The Department does not consider the definition of "genuine ownership" to be unduly vague. Additionally, while the rule does not require owners to create succession plans, it does not prevent the creation of such plans.

3. Issues the Proposed Regulations Created Related to Insurance Coverage for Care

The comment recommended that the definition of "administration session" be deleted, and that certain additional definitions be included in the rule. In consideration of this comment, the Department proposed in the List of Anticipated Revisions to the proposed rule to revise the definition of "administration session" at 7.35.2.7(A)(2) NMAC as follows:

> **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 definition more clearly delineates between administration sessions that involve the actual administration of psilocybin, and therapy sessions that do not involve psilocybin administration.

The comment includes extensive proposed revisions to the definition of "guide". The Department does not agree that the definition of "guide" exposes guides to malpractice liability. The current definition does not describe guides as performing a clinical role.

The comment includes proposed revisions to the definition of "medical services". However, this expression is based on the statutory definition at NMSA 1978, § 26-2D-3(D), and the Department cannot revise it.

3. Other Equity and Access Issues:

The comment proposes that the Department replace the written landlord approval requirement with either written approval or a lease agreement that "adequately protects the right of the program licensee to participate in the Medical Psilocybin Program." Here again, the Department believes that it is important for permit applicants and permittees to provide an attestation from a landlord acknowledging that they understand how the premises will be used. However, in response to the public comments on this subject, the Department proposes to remove the "approval" reference at section 7.35.2.8(A) NMAC, and to modify the text as stated above in Part C (5) of this letter.

The Department of Health wishes to thank the commenters who shared their expertise and perspectives in this rulemaking. While the Department has not proposed to adopt every edit suggested in public comment, the depth and breadth of feedback received in this rulemaking has informed several revisions, and has contributed to a better understanding of the rule and its impacts. The Department also wishes to thank the Medical Psilocybin Advisory Board and its committees for their pioneering work in building a safe and sustainable Medical Psilocybin Program for our state.

Sincerely,

Christopher Woodward

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Christopher D. Woodward
Deputy General Counsel