NEW MEXICO DEPARTMENT OF HEALTH

PROPOSED ADOPTION OF NEW RULE 7.35.2 NMAC

RULEMAKING HEARING

REPORT OF HEARING OFFICER

Public Hearing:	Proposed Adoption of New Rule 7.35.2 NMAC
Actions in Question:	Rule Promulgation Hearing
Hearing Date:	April 24, 2026
Report Date:	May 26, 2026

Introduction

A public hearing was held on Friday, April 24, 2026, at 9:02 a.m. in person at the Harold Runnels Building located at 1190 St. Francis Drive, Santa Fe, New Mexico and via the Microsoft Teams web conference platform and via telephone. The hearing was held for the purpose of considering the Department of Health's ("DOH" or "the Department") proposed adoption of new rule 7.35.2 NMAC ("New Mexico Psilocybin Program") in the New Mexico Department of Health's rules.

The Notice of Public Hearing

The Notice of Public Hearing ("the Notice") states that the public hearing would be conducted to receive public comments regarding the proposed new rule 7.35.2 NMAC concerning the New Mexico Psilocybin Program. The hearing was held pursuant to NMSA 1978, §9-7-6(E) of the Department of Health Act; and NMSA 1978, §26-2D-7 of the Medical Psilocybin Act. *See* DOH Exhibit No. 3.

The Notice of Public Hearing further states that the purpose of the proposed adoption of the new rule is to adopt standards for psilocybin producers and psilocybin testing laboratories in the NM Medical Psilocybin Program. The Notice lists in detail most of the individual sections of the proposed new rule, and describes what each is intended to do. *See* DOH Exhibit No. 3.

Summary of Proceedings

Craig T. Erickson presided as Hearing Officer at the hearing. The DOH was represented by Chris Woodward, Deputy General Counsel for the Department. The other participants in the hearing included the following individuals:

1. Dominick Zurlo, Director of the Center for Medical Cannabis & Psilocybin at the DOH;

2. Jacob Clark, law clerk and office manager of the Office of General Counsel at the Department.

The proceeding was recorded via Microsoft Teams, and began at approximately 9:02 a.m.

The Hearing Officer opened the proceeding by introducing himself and Mr. Woodward. The Hearing Officer also introduced Dr. Zurlo. The Hearing Officer stated that he had been appointed to act as hearing officer in this matter by Cabinet Secretary Gina DeBlassie. The Hearing Officer then explained that the purpose of the hearing was to give the public an opportunity to comment on the proposed new rule 7.35.2 NMAC.

The Hearing Office noted that, pursuant to notice, this matter was heard on the 24th day of April, in-person and via Microsoft Teams online and via telephone. Also, pursuant to notice, the Hearing Officer stated that the public had been given the opportunity to comment on the proposed rule in-person, via Microsoft Teams, and telephonically. The Hearing Officer also stated that opportunity was given to the public to submit written comments via email messages through the close of business on the day of hearing.

The Hearing Officer explained that the hearing would proceed as follows:

- Dr. Zurlo would give a brief introduction regarding the proposed new rule.
- Mr. Woodward would then introduce and move for the admission of the hearing exhibits into the record.
- The Hearing Officer would then take public comments on each section of the rule from those wishing to offer comments. Each person would be allotted five minutes to speak.

The Hearing Officer also explained that the Department is not bound by the formal rules of evidence during these proceedings. However, the Hearing Officer may, in his discretion, exclude evidence that is incompetent, irrelevant, immaterial or unduly repetitious. The Hearing Office may take notice of judicially cognizable, technical or scientific facts within the Department's specialized knowledge.

Introductory Remarks of Dominick Zurlo

Dr. Zurlo stated that essentially the new rule covers the initiation and application process for cultivators of medical psilocybin, the transportation of medical psilocybin, and the rules for applications and starting of psilocybin testing laboratories. He stated that the proposed rule has been published on the Department website and on the Sunshine portal. He noted that the Department had also posted on the Sunshine portal a list of anticipated revisions. For those who were present in-person, the list was also made available in the back of the auditorium. The anticipated revisions are for Section 7.35.2.7.

Dr. Zurlo explained that the definition of "actual control" was revised to state that actual control means the ability to (a) control the policies, management, or personnel of a permittee; (b)

control strategic priorities, capital allocations, acquisitions and divestments of a permittee: or (c) control a majority of the voting rights of a permittee. He notes that these revisions are based upon comments that have been submitted to the Department.

Dr. Zurlo then stated that the second revision is to 7.35.2.7(A)(2) NMAC. Here, the definition of "administration session" is revised to state that " . . .'administration session' means the session in which psilocybin is administered."

Dr. Zurlo next stated that 7.35.2.(I)(2) NMAC has been revised to state that "inoculate" means the process of introducing psilocybin spores or mycelium into growth medium.

Dr. Zurlo continued as follows:

7.35.2.8 NMAC has been revised concerning the application submittal requirements. The general requirements have been revised to state that an applicant for a producer or laboratory permit shall provide to the Department and shall maintain, in Subsection (A)(9), proof of ownership of the facility or 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.

7.35.2.9(C) NMAC was revised to state that restrictions on transferability of permits is not allowed by sale, assignment, or otherwise, except as approved by the Department upon the death of a sole proprietor.

7.35.2.19(E) NMAC has been revised regarding total yeast and molds action level from 20 CFU to 1000 CFU. This revision is based on the recommended limit set by American Herbal Products Association for yeast and molds in powdered dried food products.

7.35.2.19(F) NMAC has been revised to specify that water content shall be less than 10% in order to pass water content testing.

7.35.2.26(B) NMAC has been revised to specify that a 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. mail.

The table in 7.35.2.19 NMAC has been revised to modify certain pesticide testing action levels as follows:

- Abamectin has been revised from level 0.01 to 0.15.
- Bifenthrin has been revised from level 0.05 to 0.10.
- Metrafenone has been revised from level 0.05 to 0.5.

Those revisions are to correct typographic errors and to more closely reflect some of the relevant standards currently.

Introduction of the Exhibits by Chris Woodward

Mr. Woodward provided a summary of the proposed exhibits for the hearing, which had been previously submitted to the Hearing Officer. Mr. Woodward stated as follows:

He stated that the proposed exhibits were not currently available on the date of hearing DOH website, but were available on the Sunshine Portal.

DOH Exhibit No. 1: Mr. Woodward stated that this is a letter dated February 24, 2026, in which State Records gives its approval for a new chapter, Title 7, Chapter 35, Medical Use of Psilocybin.

DOH Exhibit No. 2 is the proposed new rule.

DOH Exhibit No. 3 is the Notice of Public Hearing for this rulemaking process. It is the notice of hearing for the hearing being held on April 24, with a description of the proposed rule and how public comments can be submitted.

DOH Exhibit No. 4 is an affidavit of publication from the Albuquerque Journal. It attests to the publication of the notice of hearing that was published on March 24 in the classifieds of the Albuquerque Journal.

DOH Exhibit No. 5 is an affidavit of publication for the New Mexico Register, and it attests that the notice of hearing was duly published in the New Mexico Register by State Records Center and Archives on that same date.

DOH Exhibit No. 6 is the letter appointing Craig Erickson as hearing officer in this rulemaking proceeding.

DOH Exhibit No. 7 is an affidavit from Jacob Clark attesting to the various things the Department of Health has done to comply with the notice requirements of the State Rules Act.

DOH Exhibit No. 8 is the list of anticipated revisions to 7.35.2 NMAC that Dr. Zurlo was referring to.

DOH Exhibit No. 9 is reserved for all written comments that may be submitted in this proceeding. The Notice of Public Hearing stated that the Department would accept written public comments up to the close of business on April 24, 2026.

Mr. Woodward then moved for the admission of DOH Exhibit Nos. 1 through 9. The motion was granted at hearing, and the Exhibits became part of the record in this proceeding.

On May 13, 2026, Mr. Woodward submitted a written response to the written public comments on behalf of the Department. That document was made DOH Exhibit No. 10 and the Hearing Officer admitted it as part of the record in this proceeding.

Public Comments

The following are the comments that were offered by members of the public at hearing.

Public Comment of Denali Wilson

Ms. Wilson is the state director of strategic support for the Healing Advocacy Fund, which is a nonprofit organization that supports state regulated access to psychedelic healing with a focus on access and equity within the systems. She stated that she is grateful for the Department's prioritizing this rule, and for being willing to consider recommendations that have been made to improve the protections offered by the rule.

Ms. Wilson stated that New Mexico, as a state, has really long history of economic exploitation and extraction. She stated that we all have a shared interest in making sure that this not become another place where outside money and interests come in and take advantage of our people and our resources. She stated that the amendments do not fully address this problem. Even with the changes to "actual control," the regulations continue to still broadly restrict ownership arrangements and risk unintentionally prohibit things that are beneficial and legitimate non-predatory financing arrangements, while at the same time not protecting enough to prohibit more sophisticated arrangements of disguised control or other deceitful and predatory practices.

Ms. Wilson stated that, under current draft regulations and under the proposed amendments, it is still unclear whether a party could, and if so, how they could invest in a permittee without taking responsibility for the compliance and actions of the permittee.

She argued that given the lack of traditional investment vehicles that are available in this "space," involving a Schedule 1 substance, we don't have traditional financing and banks and that lack of clarity would lock away needed capital from even friends and family investments out of local operations.

Ms. Wilson hopes that there is an opportunity to continue to "iterate on" and improve these critical and foundational protections further in the rulemaking process. She believes that the solution is not to restrict investment broadly, but instead to distinguish clearly between those who are exercising actual control over a permitted business and those who hold a more passive interest.

Consequently, her organization has offered some suggestions that reframe these distinctions in order to strengthen protections for permittees in the program from bad actors while preserving access to very limited capital in the field.

Ms. Wilson then moved to another equity issue that was discussed a lot in subcommittee and part of her organizations written feedback—what she described as the landlord attestation piece. She acknowledges that New Mexico is the first state to allow for non-property owners to

operate within the cannabis industry. She asserts that that was a tremendous stop in equity and access in the cannabis space and changed dramatically the national landscape. She is really proud to live in a state that modelled that. She also knows that it created new challenges, and she is grateful that the Department has taken an interest in making sure that we protect tenants.

However, she thinks this amendment still needs work. She argued that landlords, even those who are supportive of their tenants in the program, are unlikely to provide written approval to engage in conduct that remain federally illegal on the premises, and any written attestation would amount to written proof in a legally binding document of aiding and abetting the manufacture of a Schedule 1 substance as amended. She states that there is still reference to a landlord acknowledgement of that activity and she thinks that will be a major barrier. She thinks there needs to be a landlord lease option and the Department can specify that the lease must protect the tenant's right to participate. She states that that could include model language of an anti-illegality case that requires the landlord not to act on their right to end the contract and the lease.

Ms. Wilson was allowed to offer further comment, beyond her original five minutes, because Ms. Hanifa Washington yielded her time to allow Ms. Wilson to continue her comments regarding landlord attestation. She stated that we are talking about a federally illegal activity and something that landlords are really going to be unwilling to engage in writing. Thinking about equity and access in all aspects of the industry, she urged that the Department makes sure that small growers are able to participate. If you own the property where growers would like to grow, she would like to see us spend some time making sure that they get this right.

Her recommendation is that if there is an attestation piece that's not specifically a Schedule 1 substance, the landlords will not know whether it's acknowledgement or approval, or anything that requires a landlord to specifically endorse in some way that growing of a Schedule 1 substance on their property is going to be ill advised.

She thinks it would be most beneficial to have a lease option for landlords and tenants who would prefer to keep all protective legal agreements within the actual lease. She asserts that the Department could easily write a model lease agreement which would offer this level of protection or greater.

She argued that any access issues that are created at this juncture are going to have a foundational impact on the viability and longevity of the actual equity that people experience within the program.

In general, and on compliance and cost, she suggested that it may be helpful for the Department to consider a cost analysis for some of the testing requirements that it has outlined, as well as a compliance guide. She noted that we want people to comply and the Department does not want to enforce actions against cultivators; it would rather have people comply.

Public Comment of Kate Hawke

Ms. Hawke spoke because she wanted to ask a question. That is, she had a question about a comment that says something about selling to practitioners. She wonders whether as practitioners or medical prescribers, who are the people referred to as "guides."

Dr. Zurlo responded to the question by stating that there are placeholders at this time and there will be additional rulemaking hearings, which will be clarified at that time.

Public Comment of James Ferreira

Mr. Ferreira appeared as a representative of Ignite Synergy. He said that "everybody" has served in all the rulemaking committees, and the work has been "incredible." He stated that the speed has been unprecedented, and he thinks that for state agencies on such a topic for just a moment, you probably should not be turning your head away.

Mr. Ferreira stated that one of the things Ignite Synergy has looked at is an outcomes focused software force specifically built for psychedelics. He noted that data collection is going to be an important piece of this—of being able to actually say what our outcomes are.

He stated that we're forming a medical advisory board and they would like people to know. He said that people can contact them and let them know they would like to be on the board so that they can make some really smart decisions about data and data management. Thus, he said, when they start collecting data, it will actually mean something. This is the first time humans have ever collected this type of data, and they think it is really important.

Public Comment of Gregory Evans

Mr. Evans stated that he is an independent mycologist. He has no formal affiliations. His written public comment indicates that he is a Contributing Member of the MPAB[1] Propagation Committee. He noted that he had submitted a formal public comment on the morning of the hearing. He said he wanted to summarize the high points of that comment.

He stated that the Department had adopted the 10% water content in the rule and that is the correct direction. The water content measures total moisture; it does not measure whether anything can actually grow in the product. That, he said, would be water activity. He further stated that if the water content is at 0.6 aw most of the testing panel for microbials will not be able to grow. In addition, if we maintain cadence testing with water content and water availability, we will be able to reduce the cost to all parties with a $25 sample cost. He said that there's a lot more impact on that, but we can reduce the microbial testing by utilizing that initial release test and keeping storage within a constraint parameter.

Mr. Evans stated that there were a number of items in the traceability section that required some refinement. Further, there were areas where cultivation batch was not included in the lot

[1] Medical Psilocybin Advisory Board.

hierarchy and other section so that lot hierarchy definitions are all mapped out in the recommendation.

Mr. Evans also stated that "among the definitions I have eight amendments on a high level." He noted the corrected typo in "inoculate" and recommended a definition of "inoculate" stating that the term means the process of introducing spores, mycelium, or spawn into growth medium. He said that "inoculate" is a verb and needs to be treated as such.

He has a detailed recommendation [in his written comment] on "psilocybin" and stated he would let that stand. Mr. Evans stated that, as is the difference between cultivation and manufacture though have overlapping scope. He stated that he has also detailed how to clean that mapping and define the definition between the moment of cultivations and the moment of manufacture relating back to relating to traceability. He said that "in that section there is another definition of where unique identification numbers (UIDs) change from stage to stage." "Basically we were missing batch and then when we become a "harvest lot the definition" and the definition of that was ambiguous."

Mr. Evan stated that he has clarified the definition of "mycelium." He stated that "'mycelium' means the vegetative body of a fungus, composed of a network of filamentous structures called 'hyphae'."

Public Comment of James Brown

Mr. Brown represents Five Degree Healing Foundation. This entity is a nonprofit organization in New Mexico that focuses on veterans, first responders, PTSD, and other things. He stated that they are hoping to be a center that offers administrative sessions for whatever that definition or terminology would be. He stated that he has trained in Oregon in a psilocybin-focused 12-week program, which he thinks would be very beneficial for New Mexico to look at as we get through that program.

He stated that he wanted to focus his comments on 7.35.2.9 NMAC—the general permittee requirements. He stated that with New Mexico being such a rural state, such an amazing and beautiful state, we really have to think about that when we think about these rules. We should use that as a filter. He asserted that with this medicine that will be provided to people, they will have the opportunity to experience something that they have had experience with before, and maybe have not experienced before. Thus, his focus is on just that—"the whole dual ownership." He stated: "My whole thing today is . . . to allow us to the wording or I really think we just focus on not saying and restricting so much of that language of saying you cannot own both." As a mycologist, you are going to have these groups of people, so you can have this great network that these people can tap into. He has owned quite a few businesses and within that, you need the opportunity to grow your own business because you might have Fiber 5 [?] people within your network, like in a nonprofit, and those people might be specialists in their groups, and within that you might have a grower, a mycologist. You might also have a doctor within that same group in that nonprofit—he wants to be able to have a center.

Continuing his discussion of the rural nature of New Mexico, he noted Roswell, and Farmington, where there are only going to be some many providers, so many facilitators, so many centers.

Public Comment of John Dennis

Mr. Dennis did not appear in person; he participated in the hearing on-line. He stated that he was appearing on behalf of the Psychedelic Bar Association, which he described as a New Mexico Working Group. That group includes nine lawyers and legal professionals from across New Mexico and the United States who are volunteering their time to engage with and provide input into New Mexico's rulemaking. He stated that in order to help ensure that this program is the best that it can be, they submitted written comments. He spoke to two of the points raised in those comments.

First, he highlighted their input into "taxation" under Section 280(E) of the Internal Revenue Code. He stated that if the goal of the program is to keep costs as low as they can be under Section 280(E), liability should be really minimized to the extent possible. He stated that Section 280(E) is a tax rule that requires any organization or individual who is trafficking in a Schedule 1 or Schedule 2 substance must pay taxes and is not able to deduct the standard deductions and expenses that they incur in the cost of operating their business.

He stated that, with respect to how to minimize tax liability in the state of Oregon in its psilocybin program, the common practice is for operators to bifurcate their liability so that those portions of their operations that are plant touching or mushroom touching that would be engaged in trafficking activities are maintained separately from other aspects of the operations that are not plant touching. Thus, he asserted, all of that liability can't be isolated and contained within as small a portion of operations as possible.

He argued that this type of structuring is pretty common. He further stated that not everybody structures their organizations that way, but many do, and it substantially reduces the amount of tax liability those organizations have.

Mr. Dennis stated that they understand that there is a very legitimate state interest in avoiding diversion and similar types of behaviors, but there are a series of protections and guardrails that should go around this. He stated that is, the facilitator or guide is not actually delivering the substances to clients or patients, that would enable those multiple hours, potentially as many as ten hours per administration session to not be taxed at this significantly higher level.

Thus, Mr. Dennis argues that if the state were to allow some kind of abbreviated touch point with the actual transfer of psilocybin to the patients directly, it could provide an opportunity to save costs, and reduce the tax burden.

Mr. Dennis argues that this is a really significant aspect of this, and it is more significant for those who are familiar with the way that Section 280(E) plays out in the cannabis space. With cannabis, it's just retail, so you're not really having to pay for hours of support and supervision and facilitation and that sort of thing. Consequently, he stated, the impact that Section 280 (E) has

on a regulated services model such as New Mexico's is significantly more than it is even in the cannabis space. Thus, allowing these direct sales, or some interim person who is not otherwise providing like hours of service to patient, is a pretty good opportunity to keep costs low and keep it as affordable as possible.

Mr. Dennis then turned to the second point he wanted to discuss. He noted that the written comments he submitted speak about the accidental, potentially inadvertent, authorization of religious use in the state of New Mexico by the passage of the Medical Psilocybin Act. He stated that they cited three cases in their written materials that stand for the proposition that if the State of New Mexico or any state is authorizing legal psilocybin access for any reason, it then under current US Supreme Court precedent must also authorize religious use of that substance. Thus, he requested that the religious use cases should not be disparaged in this process, and to the extent that this could result in potential harms that can come from community use in unregulated or unsupervised settings, the state may wish to take action to ensure that there are safeguards and there is some kind of support.

Participants who were present for the hearing but did not make public comments include the following:

1. Chris Peskuski
2. Clifford M. Rees
3. Gabriel Smith
4. Julie S_k__
5. Tyke Pinch, Jaded Janes
6. Celeste Lugan, Jaded Janes
7. Michael Williams, Limina Foundation
8. Toby Rosenblatt, NMDOH
9. Hanifa Washington, PMHA Alliance
10. Brenda Bangard, DOH Advisory Board Member Chair
11. Skye Rivers, Santa Fe Reporter
12. David Barre, NMDOH
13. Gregory Burgard, NMDOH
14. Breanna Wunder, El Centro Family Health
15. Mateo Frazier, COSMICA, LLC

There were no further, on-line public comments, and no comments from telephonic participants.

The Hearing Officer then explained that he would be writing a report to the Cabinet Secretary, in which he would summarize the public comments offered at hearing as well as the written comments that had been submitted to the Department. He would then make a written recommendation to the Cabinet Secretary regarding the proposed new rule.

The Hearing Officer thanked the participants for their public statements and adjourned the hearing.

Written Public Comments

The following is a summary of the written public comments[2] submitted in this rulemaking process:

The Written Public Comment of James Brown

Mr. Brown recommended that the Department adopt definitions for several terms, as follows: "referring clinician," determining clinician," "guides or facilitators," and "integration provider. He asked for guidance regarding who these people would be, i.e., physicians, certified nurse practitioners, physicians assistants, psychiatrists, or other specialized clinicians. *See* DOH Exhibit No. 9.

Mr. Brown also proposed that the Department incorporate additional text in the rule to require three classes of recalls.

He further recommended that the prohibition against dual ownership by a permittee be modified to allow a person who holds either a producer or laboratory permit to hold an interest in another permittee, as long as there is a clear separation between each permittee's operations.

The Joint Public Comment: Proposed Propagation Regulations of the Healing Advocacy Fund and the Rudick Law Group[3]

This public comment was submitted by Denali Wilson, Esq., and Victoria Cvitanovic, Esq.[4] on behalf of the Healing Advocacy Fund and the Rudick Law Group. *See* DOH Exhibit No. 9. They focused on compliance implementation, financial feasibility, and liability reduction for all parties involved, and asserted that addressing those areas thoroughly will dramatically impact equity and access within the program.

The authors of this comment noted the novel nature of New Mexico's Psilocybin Program. They argue that the regulatory decisions made now will shape the Program's safety, integrity, accessibility, invest ability, and equity for years to come. The authors state that they approach their comments from a place of commitment to the success of the Program and a sincere commitment to accomplishing the goals of the Department. They assert that they applied a critical lens to their comments, asking how opposing counsel, investors, financiers, and others could use the draft regulations to undermine the goals of the Department to protect operators, patients, and providers to further their own interests.

The authors state that their 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;

[2] All of the written public comments are located in DOH Exhibit No. 9.
[3] Designated as the "Joint Public Comment" herein.
[4] Hereinafter collectively referred to "the authors."

4. Other equity and access issues; and
5. Issues the proposed regulations create related to insurance coverage for care and professional liability insurance.

For each of the foregoing areas, they offer recommended action. The authors assert that the issues here are serious, and if left unaddressed, they present meaningful risks to safety, stability of the supply chain, accessibility, and participation in the regulated Program. These risks, they argue, could undermine the goals the Program was designed to achieve.

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

The authors state that "predatory financing" can be defined as any financing arrangement in which the economic terms, structural features, or contractual conditions 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.

They further state that 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 authors urge that the rules should not be so broad that they discourage the capital formation that Program participants need.

They argue that two primary harms result from predatory financing: economic extraction and disguised control. They suggest that 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. They argue that business participating in state programs that allow otherwise federally illegal conduct are particularly vulnerable to the foregoing risks, as these businesses are often excluded from traditional financing.

The authors state that 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 may be achieved through covenant packages, exclusive supply or service agreements bundled with the financing, board observer rights, or consent rights over material business decisions.

The authors argue that a predatory lender may gain leverage through punishing economic terms, and then use that leverage to exercise de facto control. These issues are not disclosed to regulators because the party never appears as a licensed owner, and the financing arrangement becomes the mechanism for regulatory evasion.

The authors state that 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?" The authors state that, if so, that arrangement should require permittee-level disclosures and responsibilities that flow to the financier, or it should be prohibited.

The authors state that, because psilocybin is a Schedule 1 substance under federal law, most lending institutions will not provide financing to businesses operating in this arena. Consequently, most operators are dependent on private capital arrangements, and carry significant risk of exploitation. Similar dynamics exist in the cannabis industry, and have contributed to widespread hardship, forced bankruptcies, and the erosion of equity goal in state-regulated programs.

The authors observe that the draft regulations attempt to address these risks by broadly restricting ownership arrangements and transfers of control. However, they argue that this approach is overly broad in ways that would unintentionally prohibit beneficial arrangements—such as friends-and-family investment, and legitimate minority ownership stakes, thereby destabilizing 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.

The authors believe that the solution is to distinguish clearly between those who exercise actual control over a permitted business and those who hold a passive financial interest. They offer suggested amendments to the draft rules to address those concerns.

The authors propose a much more detailed definition of the term "actual control" that is set forth in the proposed rule by the Department found in 7.35.2.7(A)(1) NMAC. The authors' proposal is found on pages 3 - 4 in the authors' Joint Public Comment in DOH Exhibit No. 9.[5] The authors argue that their proposal defines "actual control" in a clear, enforceable manner that can be used to address permittees' compliance, and defines "true party in interest" to ease the identification of actual control, and further defines "minority participant" to define people and entities who have a meaningful connection to a permittee but who does not have actual control over, or responsibility for, the actions of a permittee.

The authors also propose a new subsection, which they designate as 7.35.2.7(A)(2) NMAC, which would provide for the principle that aggregated influence should be an express consideration in the application of the rule. *See* the Joint Public Comment at page 4 in DOH Exhibit No. 9.

The authors argue that their proposed definition of "actual control" moves away from the "ability" to take certain actions, which they argue 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. They assert that this makes the definition easier to administer, and harder to evade through creative structuring.

The authors next turn to the definition of "genuine ownership" at 7.35.2.7(G)(1) NMAC. They argue in favor of striking this definition, and replacing it with several new definitions for the rules—one definition for "true party in interest," another for "minority participant," and several more "associated' regulations. *See* pages 5 - 7 of the Joint Public Comment found in DOH Exhibit No. 9 for the complete proposal.

[5] Given the length of the authors' proposed rules, they are not summarized here. The reader should review the authors' proposed rules DOH Exhibit No. 9.

The authors argue that the Department's proposed definition for "genuine ownership" is vague and may invite litigation. Further, they argue that the proposed definition is unclear as to how a party can contribute to a permittee if they wish to minimize their own risk. They argue that this dynamic will limit the pool of investment available to permittees, and even exclude friends and family who may wish to assist without acquiring responsibility for controlled substance cultivation. The authors argue that my defining two distinct categories or participation, the Department can regulate actual control, avoid disguised control, prevent predatory financing, and encourage investment.

In addition, the authors suggest that the Department may well require registration and disclosures from "minority participants" even though they are not true parties in interest. They state that their suggested definition contemplates the addition of "minority participant" responsibilities, even if those responsibilities do not rise to the level of what is expected from a true party in interest.

2. Clarity regarding rules into investment into permitted businesses;

The authors of the Joint Public Comment turn next to issues related to the clarity of the rules related to investment into permitted businesses. *See* Joint Public Comment in DOH Exhibit No. 9 at pages 8 to 11. They argue that in the current draft regulations, the "General Permittee Requirements," (which they cite as 7.35.2.1 NMAC but is actually 7.35.2.9 NMAC), it is unclear whether and how a party could invest in a permittee without taking responsibility for the compliance and actions of that permittee. They argue that given the lack of traditional investment vehicles available to permittees, such ambiguity could lock needed capital out of local operations, (for example, capital from friends and family investments).

The authors include a proposed rule, designated as 7.35.2.2 NMAC, to replace rule 7.35.2.9 NMAC, the General Permittee Requirements. *See* Joint Public Comment at pages 9 – 11 for the proposed amended rule. They argue that the proposed rule should be amended in the manner proposed by their amended rule because by tying the dual ownership prohibition in the Department's proposed rule to true party in interest 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. They argue that this approach 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 authors state that the original proposed rule of the Department broadly prohibited any transfer of actual control through management, consulting, or intellectual property agreements. They argue that while the intent of the Department was sound, the proposed rule created compliance uncertainty for legitimate arrangements, such as shared services agreements between related entities. They also argue that the lack of a succession provision created significant liability concerns for spouses, children, and others who may be left with possession of Schedule 1 substance cultivation facilities and no legal permit in the case of the death of a true party in interest.

The authors argue that their revised framework addresses the underlying undue influence concerns while protecting legitimate investors, friends and families, and business partners. They argue that no person should have to worry if their spouse or business partner dies, or if any entity dissolves through no fault of their own, that they are suddenly and irrevocably in possession of Schedule 1 cultivation with no legal protection.

The authors argue that the disguised control provision does the core work of the predatory financing protections; it prohibits any arrangement through which a person who is not a true party in interest exercises actual control over a permittee. They argue further that by framing the prohibition around function rather than form, their amendment closes the drafting gaps that sophisticated actors would otherwise exploit. Finally, as to this issue, they argue that their suggested amendment expressly allows minority investment while making clear that investment cannot be a vehicle for "back-channel control."

3. The feasibility, costs and risks of compliance posed by the draft rules;

The authors' next focus addresses overall compliance feasibility and clarity. *See* pages 11 - 13. The authors state that the Department's proposed regulations establish requirements for product traceability, food safety, and contaminant testing which are essential to patient safety in the regulatory access program. They support the inclusion of these rules. They do not cite the specific rule they refer to; however, they appear to be referring at least to Subsections 7.35.2.16, 17, 19, 20, and 21 NMAC, and perhaps others.

The authors argue that certain proposed regulations may exceed what patient safety requires. Others, they argue, fail to provide operators with a clear, administrable compliance standard. They argue that both problems carry real costs, and overly burdensome or redundant testing requirements will drive up production costs that will ultimately be passed on to patients, or absorbed by the State and deplete the Treatment Equity Fund. They assert that where compliance standards are vague, operators cannot reliably meet them, which creates enforcement uncertainty and legal exposure for good-faith participants in the program.

With respect to the issue of cost feasibility, the authors recommend that the Department conduct and publish a cost analysis of the testing and production requirements as currently drafted in the Department's proposed rule before the regulations are finalized. They argue that it is likely that some requirements will need to be recalibrated as the program matures. Consequently, they recommend that the Department build implementation review metrics into the program from the outset which would track 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 the issues of compliance clarity, the authors assert that where the Department's proposed regulations are ambiguous or undefined, operators are left to guess at what conduct will satisfy the requirement. They argue that this will create inequitable enforcement; operators with more resources can obtain legal guidance—those without more resources cannot. This dynamic will expose good-faith operators to disciplinary action for conduct that reasonable actors could interpret as compliant. Thus, they argue the Department should review the draft regulations for

undefined compliance standards, and either specify the required conduct directly in the text of the regulations or commit to publishing guidelines along with the final regulations.

They argue, as an example, that the following original proposed rule and their suggested amendment illustrates their point. The original proposed text for 7.35.2.21(B) NMAC ("Wastage of Psilocybin and Psilocybin Products: Permitted"):

> 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.

The authors suggest amendment of the foregoing proposed rule:

> 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.

The authors state that amendment of the rule should be considered because, where the Department's proposed rule prescribes wastage by "destroying" the product, it does not prescribe the means of destruction that are permitted, leaving cultivators to guess what process of destruction is permitted. They state that Oregon and Colorado state program operators suggest that heat or freeze treatment is a viable, cost-conscious means of product wastage.

The authors next address 7.25.2.10(A) ("General Producer Requirements"). *See* pages 13 14 of the Joint Public Comment in DOH Exhibit No. 9, wherein the authors offer a substantial revision to the Department's proposed rule. The authors' suggested amendment appears to be an unfinished and unedited proposal. *See* DOH Exhibit No. 9, *id.*, at page 13. Consequently, their intent is ambiguous and unclear.

Their argument, however, is that the proposed 7.25.2.10(A) NMAC sets out what a producer is required to do, but does not explicitly define who is eligible to become a producer. ["Psilocybin producer" and "producer" are defined in 7.35.2. 7(P)(13) NMAC.] They argue that this perceived gap creates compliance uncertainty at the threshold of program participation. They further argue that operators cannot reliably assess their eligibility before investing in an application, and the Department lacks a clear regulatory basis for consistent eligibility determinations.

They further assert that a related ambiguity concerns dual licensure. They assert that the Department's proposed regulations do not address whether a cultivator currently licenses under New Mexico's Cannabis Program may also hold a producer license under the Psilocybin Program. They argue that this silence is likely to create unnecessary barriers for a class of operators who among the best positioned to participate in the Psilocybin Program—cannabis cultivators who already have the compliance infrastructure, existing relationships with state regulators, and demonstrated capacity to operate in Schedule 1 adjacent regulated environment.

4. Other equity and access issues

The authors next addressed what they perceive to be a problem with 7.35.2.8(A)(9) NMAC, which requires applicants to provide "proof of ownership of the facility or written approval from the owner to cultivate psilocybin on the premises." The authors assert that while they 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.

They argue that landlords, even those who support tenants who are part of the Program, are unlikely to provide written approval to engage in conduct that remains illegal under federal law on their premises; such attestation would amount to written proof in a legally binding document of aiding and abetting the manufacture of a Schedule 1 substance and would expose landlords to civil and criminal liability. They also argue that the requirement creates an opening for exploitation—a landlord who is familiar with the requirement could use that as leverage to extract unfair terms or higher rents from tenant seeking to operate in the Program.

The authors suggest the following amendment:

> [An applicant for a producer or laboratory permit shall provide to the department and shall maintain the following records] . . . 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.

The authors argue that their proposed amendment addresses the concerns that they have raised by replacing the written approval requirement with three alternatives that provide equivalent regulatory assurance without requiring landlords to attest to aiding and abetting activity under federal law. The 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 Program, or an attestation allowing for Program participation rather than requiring a landlord to attest that the permittee may cultivate psilocybin on the property regarding of Program participation.

The authors further argue that if one considers the situation where a permit is revoked, under the current language, a permittee could "pivot a landlord's premises into illegal production relying on the same attestation the Program required to prevent eviction." *See* page 15 of the Joint Public Comment in DOH Exhibit No. 9.

The authors argue that, under the amendment, where a landlord's approval is still sought, the amendment narrows the scope of that approval to participation in a licensed DOH program, which reduces that landlord's legal exposure and also preserves the Department's ability to verify site access. Further, they assert that the lease agreement pathway reflects established practice in industries that operate legally under state law, but remain subject to federal prosecution. They assert that in those industries, it is standard for tenants and landlords to negotiate an anti-illegality waiver, in which a landlord voluntarily waives the right to void the lase to the basis of the tenant's

legal state activities but federally prohibited activities. They argue that the 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 lessee fails to comply with the state program which both parties rely on to reduce their liability. They suggest that the Department could publish a model lease clause to establish a baseline standard.

5. *Issues the proposed regulations create related to insurance coverage for care and professional liability insurance.*

In the last section of their public comment, the authors address issues the proposed regulations create related to insurance coverage for care. *See* DOH Exhibit No. 9, pages 15 - 16 of the Joint Public Comment. The authors argue that the Department must address how to structure a care model that preserves insurance coverage for the services patients are already entitled to receive. Thus, they argue that the Department must help to define a new insurance market. They argue that how the components of the Program are described in the regulations will directly determine what arguments third party payors will use as grounds to deny coverage. Where the regulations are ambiguous, they argue, insurers will exploit that ambiguity, and the resulting costs will fall on patients and providers.

The authors assert that most Medicaid and third-party payer contracts contain provisions that prohibit coverage for services provided in connection with an "unapproved treatment modality." *Id.* at 15. Thus, for Psychedelic Assisted Therapy, the unapproved treatment modality is the actual administration or self-administration of a Schedule 1 substance. This prohibition means that any service the regulations define as part of the administration of a Schedule 1 substance will likely not be paid by any insurance company, whether it be government or private insurance.

The authors note that the proposed 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." The authors argue that coverage planning becomes difficult, even impossible, when unapproved and normally covered components of care are combined in the language of the regulations. They further argue that 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 payors cover in virtually every other clinical context, and should be recoverable here. However, the authors assert, the proposed regulations describe these services in ways that tie them to the administration of psilocybin, creating a basis for insurers to treat the entire continuum of care as part of an unapproved treatment modality, and then declining coverage. They argue that the solution to this issue is to ensure that the regulatory definition describing preparation and integration services stand independently of the administration of psilocybin.

The authors assert that there is a second risk arising out of the proposed regulations. That is, that New Mexico faces professional liability questions which have no precedent and no established insurance framework for a medically-integrated state psilocybin program. The authors state that these issues are made more urgent and 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. They assert that the regulations must now be read against a liability landscape that has shifted since the underlying statue was written.

The authors note that the Program is dependent on clinician participation. The fewer clinicians who are willing to take the risk of participating, the less accessible the Program care will be. The risk implicates their clinical licensure, prescriber licensure, and long-term insurability. The authors argue that by tying "administration" to the other care a clinician might provide, the regulations increase the risk of discipline, loss of license, or having their insurance dropped. Thus, they argue that a clear separation between Schedule 1 administration and other care is required to protect the clinicians who will build this Program.

The authors state that the problem is that where a regulation or statute describes the administration of a Schedule 1 substance as the provision of "medical services" that characterization risks bringing such activities within the scope of the Medical Malpractice Act. The authors assert that this creates a serious coverage gap because medical malpractice insurance covers claims arising from the provision of medical services, but insurer underwriting those policies did not price and will not cover claims arising from the administration of a substance that is illegal to possess, manufacture, sell, or distribute under federal law. The authors argue that providers could find themselves subject to malpractice liability obligations for activities that their malpractice carrier will not cover—leaving them personally exposed in the event of a claim.

The authors state that they recognize that some of the professional liability issues identified in the draft regulation arise out of the Medical Psilocybin Act itself. They suggest that full resolution of those issues may require statutory amendment. They note that the Ruddick Law Group is preparing a memo on medical malpractice liability under the MPA that will address legislative recommendations. They argue that addressing these issues proactively in the regulations will provide meaningful clarity for providers now and avoid the need to revise the regulations to conform with future statutory changes that are likely necessary.

In order to address these issues, the authors have suggested amendments to the regulations that are addressed in detail on pages 17 - 19 of the Joint Public Comment in DOH Exhibit No. 9. They recommend striking the proposed 7.35.2.7(A)(2) NMAC, which states that "'administration session' means the therapeutic session combined with the administration of psilocybin." They then recommended replacing that definition with the following proposed regulations:

- "Program" means the New Mexico Psilocybin Program established under the Medical Psilocybin Act.

- "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.

- "Administration" means the act of a Program Participant ingesting psilocybin within a context authorized by the Program, exclusive of an Other Care provided before, during or after that ingestion.

- "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.

The authors argue that by combining therapy with the administration of psilocybin in the draft regulation, the state invites Medicaid and other third-party payors to decline coverage for behavioral health care they would otherwise cover, creating affordability and access barriers that harm the long-term viability of the Program. They argue that the amendments they propose reframe the program components in ways that protect the patient's best chance at accessible care and protect clinicians from avoidable risk.

The authors state that if the amendments they propose are adopted, the definition of "Guide" will also have to change. They argue that the definition of "Guide" as proposed in 7.35.2.7(G)(3) NMAC, invites allegations of the unauthorized practice of medicine. This would, they argue, further undermine a clinician who works with a Guide's ability to maintain licensing and insurance while participating in the Program. They argue that if Guides are assisting in the provision of clinical care, there is a potential for attempts at tying medical malpractice liability to Guide services.

As proposed in 7.35.2.7(G)(3) NMAC, a "Guide" is "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."

The authors suggest that the definition of "Guide" be amended to state the following:

> "Guide" means an individual who has complete 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.

The authors assert that the core problem with the proposed definition of "Guide" by the Department is that the phrase "assist practitioners during the "administration session" implies a subordinate, clinical relationship that could expose guides to malpractice liability for clinical acts they are not licenses to perform, or creating a supervisory relationship that makes the practitioner responsible for the guide's conduct in ways neither party intends.

Finally, the authors address the definition of "Medical services" in the proposed regulations. As proposed in 7.35.2.7(G)(2) NMAC, "'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."

The authors propose to revise the draft rule as follows:

> "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.

The authors argue that the Department's proposed rule has two problems. One, it collapses administration and other care into a single undifferentiated concept. And two, the phrase "medical services" implies a clinical character for all Program services, including Administration. This, they argue, creates potential insurance, supervisory, malpractice, and other concerns which will likely reduce clinical participation in the Program.

The Written Public Comment of John Starr on Behalf of Strong Medicine

John Starr submitted a written public comment on behalf of Strong Medicine. *See* DOH Exhibit No. 9. He articulated concerns about the ability to justify investment with the proposed limitations. He asserted that the majority of those interested in psilocybin growing businesses are small businesses. He noted that it is well-documented that most small businesses fail due to lack of working capital. He argued that the proposed rules will limit encouraging investment to the extent that significant failures are likely. He argued that this will restrict access to the product for medical purposes, and will set the stage for making the price of the medicine out of reach for many of the patients who need it most.

Mr. Starr asserted that the recent announcement of the federal government to reconsider the Schedule 1 drug list adds uncertainty in the investment world, pushing the pause button on any future investment plans. He raises the question as to what safeguards prevent the Program from becoming too expensive for patients or too unprofitable for producers.

Mr. Starr stated that the Joint Public Comment that was submitted by Ms. Wilson and Ms. Cvitanovic echoes many of his concerns as to ownership and investment. He refers to a quote from that comment: "The rules should not be so broad that they discourage the capital that participants in the Program need." He hopes that in the spirit of equity, being a businessman is not seen as a bad thing.

The Written Public Comment of the Psychedelic Bar Association

Jonathan Dennis, Esq., submitted a written public comment on behalf of the Psychedelic Bar Association (PBA) New Mexico Working Group. *See* DOH Exhibit No. 9. Mr. Dennis stated

that the PBA is a 501(c)(3) nonprofit association of lawyers and legal professionals that is committed to the creation of a world where safe, legal access to psychedelics brings healing, equity, and justice for all. He stated that PBA's comment focuses on 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, and
5. Restrictors for Property-renting Applicants.

A summary of the foregoing issues follows:

Principles of Regulation

Mr. Dennis states that in the right setting, the psilocybin experience ranks among the top five most personally meaningful and spiritually significant experiences of a person's life. He argues that it is paramount that the Medical Psilocybin Program be affordable and accessible to everyone who could benefit. He states that failure to achieve that goal will deprive low- and middle-income communities from astonishing health and life outcomes.

Mr. Dennis stated that the key considerations for a regulatory framework that is designed to be affordable and equitable include the following:

- The safeguards must be proportionate to safety concerns. He argued that if safety requirements are higher than necessary, costs will be raised to the detriment of low- and middle-income communities. He proposes that screening questionnaires that identify potential contraindications can inexpensively resolve safety concerns. For example, Guide's supervision does not need to be by person with advanced credentialing.

- Rulemaking should be governed by informed consent principles. Mr. Dennis argues that potential harms of most psychedelics are lower than, but different from, alcohol and nicotine, "which we trust adults to use responsibly without excessive paternalism." *See* PBA's written comment at page 2 in DOH Exhibit No. 9.

- Rulemaking should embrace or allow psychedelic use in a community-based paradigm, making liberal use or peer support in preparation, administration, and integration services. He argues that this will promote affordability, cultural sensitivity, and inclusivity.

- Over-regulation of psychedelic substances should be avoided. He states that Oregon provides a cautionary tale—a gram of one brand of regulated mushroom sells for $40 to $50, whereas a similar unregulated brand sells for $8/gram. He asserts that the costs in Colorado are also high. He argues that the harms sought to be avoided by the proposed draft rule 7.35.2.19 NMAC (Required Testing of Psilocybin Products) have not materialized in Oregon or Colorado.

Mr. Dennis argues that psychedelics are not conventional Western medicine and do not fit easily into Western models of praxis. He argues that current attempts to induce mystical experiences in a doctor's or therapist's office using psychedelics are absurd, and should be left to religious and indigenous communities.

Intersections of Medical and Religious Use

He argues that one of the most critical questions facing the rule makers is what attitude the proposed rules will express toward religious use cases. He argues that New Mexico should not disregard religious adherent's claim to legal access. He states that New Mexico adopted broad religious freedoms that allow religious practitioners to use psilocybin and other psychedelics in the practice of sincere religious exercise, citing NMSA 1978, §28-22-3, *et seq.* He argues that regardless of the religious freedom that the State has intentionally enacted, the passage of the MPA has created a system for granting individual exceptions to the NM Controlled Substances Act. He argues further that when a state adopts a system for granting individualized exemptions to any law, the First Amendment to the U.S. Constitution requires that exemptions to that law also be granted for religious practitioners. He argues that this means that a state cannot authorize legal access to a drug for medical reason without also authorizing legal access to that drug for religious reasons.

Mr. Dennis argues that the issue was recently litigated in *Jensen v. Utah County,* U.S. Dist. Court for the District of Utah, Case No. 2:24-cv-00887-JNP. He asserts that the judge ruled in that case that the Utah Controlled Substances Act was not generally applicable with respect to psilocybin and found that the First Amendment protects religious activities involving psilocybin in Utah.

Mr. Dennis states that while the PBA does not have particular recommendations with respect to this round of proposed rules, they urge the DOH to be proactive in not undermining religious practitioners in its policies and regulations.

Sale Restrictions and Federal Tax Consequences

Mr. Dennis states that service providers in Oregon 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 1 controlled substance from deducting ordinary business expenses on their federal taxes. Consequently, businesses with any direct involvement in handling or transferring psilocybin must pay federal income tax on gross revenue rather than net income, significantly increasing their effective tax burden.

Mr. Dennis asserts that Oregon and Colorado both operate supervised-use models similar to the model New Mexico is building. In those programs, he states, psilocybin is not sold directly to program participants through dispensaries; it is transferred to service centers that administer it to participants under supervision. He states that this transfer from producer to service center triggers Section 280(E) exposure for the service center. He states that operators in both states have attempted to minimize this tax exposure by creating separate legal entities to isolate plant-handling activities from their other business operations so that Section 280(E) liability does not contaminate

the tax treatment of the entire enterprise. He notes that this approach has not been evaluated by the courts, and it is uncertain whether it would survive judicial scrutiny. He also asserts that it is a costly and administratively burdensome strategy that disadvantages smaller operators and adds overhead to a highly-regulated industry.

Mr. Dennis argues that, as drafted, the proposed regulations replicate the same sale structure that has created these tax problems elsewhere, and they do not take advantage of the opportunity to build in structural flexibility before the problem materializes. He argues that allowing direct sales from producers to patients at an approved location and while under the supervision of a guide would dramatically reduce the impact of Section 280(E) while avoiding diversion and related concerns.

He proposes the following amendments to 7.35.2.10(B)(7) NMAC ("General Producer Requirements"), as indicated by underscoring:

> 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.
>
> 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.

Mr. Dennis states that the foregoing proposed amendments introduce a direct participation sale option as an alternative pathway alongside the producer-to-practitioner model. This would allow the direct sale of psilocybin to a program participant so long as the sale occurs at an approved location on the day of administration and consumption takes place in the presence of a licensed clinician or guide.

He argues that the tax consequence of this proposal is significant. He argues that when the sale runs directly from producer to patient, the service center is not a party and therefor not engaged in trafficking under Section 280(E). He argues that this would allow the service centers to deduct ordinary operating expenses and reduce the tax penalty that would otherwise fall on them.

He states that the proposed amendment would not require the use the direct sale model; it creates an option to do that.

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

Mr. Dennis advocates for a goal of designing a regulatory framework that supports good-faith actors and limits the ability of bad-faith actors to cause harm by being primarily motivated

by profit, or seeking to exploit regulatory gaps for financial gain. He argues that the proposed regulations fall short of that goal by being broad enough to burden legitimate arrangements, including friends and family investment, minority ownership stakes and other financing structures that small operators depend upon, while leaving more sophisticated disguised control mechanisms that present the greatest patient risk inadequately addressed.

Mr. Dennis addresses 7.35.2.9(B) NMAC ("General Permittee Requirements—Dual ownership prohibited") which prohibits a person from holding an ownership interest in a permittee from having an ownership interest in any other permittee. He appears to support that provision. However, when additional regulations are adopted, he hopes the DOH will not prohibit producers from functioning as a guide or serving other roles within the Program.

He then turns to draft rule 7.35.2.26(C)(m) NMAC ("Disciplinary Actions and Appeal Process—Grounds for disciplinary action"), which provides as follows:

> Disciplinary action may be taken against a permittee or a permit-applicant . . . [and] 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.

Mr. Dennis also cites the definition of "genuine ownership," found in 7.35.2.7(G)(1) NMAC, which states as follows:

> "Genuine ownership" means ownership interest in an applicant or 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.

He argues that these regulations create an unclear standard that would appear to penalize permittees who have passive investors who do not have authority for decision-making. He argues that would be problematic given the available pool of funding that is available to federally illegal businesses.

Mr. Dennis proposes that the solution to this issue is to clarify that passive investments are allowed within the program. He argues that requiring all investors to have decision making authority can result in "mission drift" and undermine the medical goals of the Program; business decisions should be made by those who are actively involved in the provision of care.

<u>Restrictors for Property-Renting Applicants</u>

The PBA supports the comment submitted by Healing Advocacy Fund and the Rudick Law Group regarding the requirements for property-renter cultivators in 7.35.2.8(A)(9) NMAC

("Permit Application Requirements"). Mr. Dennis states that the PBA supports the proposed amendment to add a lease agreement, with anti-liability waiver. They also support revising the scope of the written approval option to require only attestation of permission to participate in a licensed Department program, rather than permission to cultivate psilocybin on the premises. He argues these changes would reduce the legal exposure to landlords.

The Written Public Comment of Gregory Evans

Mr. Evans is an Independent Researcher and Contributing Member of the MPAB Propagation Committee. He submitted written public comments on the proposed rule. *See* the written public comments of Mr. Evans, which include a Document Package Summary, a Public Comment, and Addendums A, B, and C, in DOH Exhibit No. 9. While Mr. Evans' comments are extensive, they are also quite focused and succinct as to each subsection of the rules which he addresses. Thus, they are addressed in the summary of the Department's written response to the public's written comments, which follows this section of this report.

The Written Response of the Department to the Written Public Comments

The Department responded to the written public comments in a letter dated May 13, 2026, from Mr. Woodward. *See* DOH Exhibit No. 10.

The Department responded to the written public comments of James Brown as follows:

The Department responded to Mr. Brown's comments on recall classifications. Mr. 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 stated its belief that the proposed text at 7.35.2.10(A)(8) NMAC and 7.35.2.19(M)(1) - (5) NMAC is sufficient and provides 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 text. The Department is also concerned that Mr. Brown's proposed text would unnecessarily complicate the recall process.

The Department also responded to Mr. Brown's recommendation to adopt definitions for various terms and utilize them in the rule. The Department stated that the Dosage, Administration & Clinical Practice 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 states that it anticipates addressing these matters in future rulemaking.

The Department responded to Mr. Brown's recommendation that the prohibition against dual ownership by a permittee be modified to all a person holding either a producer or laboratory permit to hold an interest in another permittee, so long as there was a clear separation between the operations of each permittee. The Department stated that it believes that allowing persons who have ownership interests in a permittee to hold ownership interest in other permittees can raise various conflicts of interest that would be detrimental to patients in the Program; one of the biggest conflicts is the potential for market monopoly. Another arises in the case of dual ownership in a producer and a laboratory which could incentivize the skewing or falsifying of test results.

The Department also responded to the written public comment of Denali Wilson and Victoria Cvitanovic, the authors of a comment submitted on behalf of the Healing Advocacy Fund and the Rudick Law Group (the Hearing Officer refers to them as "the authors" in this report.) *See* DOH Exhibit No. 10. The Department first addresses the authors' comments regarding gaps in protections against predatory financing and disguised control. The Department responded to the authors' proposed amendments to limit the potential for predatory financing and strawman-type arrangements within the Program, which included the proposed edits to the definition of "actual control" and the proposed deletion of "genuine ownership." The Department states that in consideration of this comment, it proposed a revised definition of "actual control" in its List of Anticipated Revisions.

The Department notes that transfer of actual control would be prohibited under the proposed 7.35.2.9(D) NMAC. In the proposed, revised definition of "actual control," whether someone has "actual control" over a permittee depends on whether they can dictate the policies and priorities of the permittee—not whether they can "exert authority" over the permittee. The Department asserts that the revised text would enable someone who has an ownership interest in a permittee to vote their shares, exerting an influence on the business without having absolute control over it. The Department further asserts that the revised text is consistent with 7.35.2.9(E) NMAC, which effectively requires 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 states that it believes the revised text of the rule is relatively straightforward and adequately addresses the subject of ownership interests in a permittee. It further asserts that the text proposed by the authors, which included lengthy revisions to the definition of "actual control" and multiple passages regarding "true parties in interest" would be overly complicated and not add significant value.

The Department also commented on the authors' comments regarding clarity regarding rule into investment into permitted businesses. The Department notes that the author's comment included various proposed edits to 7.35.2.2 NMAC, "General Permittee Requirements." The Department argues that these proposed edits would overly complicate the rule, again, without significant value. The Department argued that 7.35.2.9(B) NMAC prohibits 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 Department states that the authors' comment would permit dual ownership so long as the person does not qualify as a "true party in interest" with respect to the second permittee. The Department argues that prohibiting dual ownership is a more robust, practical approach to limiting predatory financing and disguised control of the premises. The Department argues that prohibiting dual ownership and requiring record ownership provide bright-line standards that are simpler for the Department to enforce and easier for regulated entities to follow. The Department also asserts that shifting to an entirely control-based approach would be difficult to implement; it would be difficult to distinguish between persons who are simply passive investors and person who exert control over a permittee through backroom decision-making.

The Department also responds to the authors' comments on issues the proposed regulations created related to insurance coverage for care. The Department notes that the authors recommended that the definition of "administration session" be deleted and that certain additional Definitions be included in the rule. The Department states that in consideration of this comment, it proposed a revised definition of "administration session" in its List of Anticipated Revisions."

The proposed revised rule 7.35.2.7(A)(2) is as follows:

> "Administration session" means the [~~therapeutic session combined with the administration of~~] session in which psilocybin is administered.

The Department argues that the revised, proposed rule more clearly delineates between administration sessions that involve the administration of psilocybin and therapy session that do not involve the administration of psilocybin.

The Department responds to the authors' extensive proposed revisions to the definition of "guide." It does not agree that the definition of "guide" exposes guides to malpractice liability; the current definition does not describe guides as playing a clinical role.

Finally, the Department responds to the authors' comment's proposal 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." The Department asserts 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. As noted in the discussion of the Department's List of Anticipated Revisions, however, the Department proposed to remove the reference to "approval" in 7.35.2.8(A) NMAC, and modify the text as stated above.

The Department also submitted a written response to the written public comment of John Starr. *See* DOH Exhibit No. 10 at pages 6 -7. The Department notes that Mr. Starr stated that rules should be written in a manner to favor 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 stated in response that it believes the proposed rule strikes an appropriate balance between ensuring the safety of psilocybin products and avoiding the imposition of unnecessary expenses and restraints.

The Department also submitted a written response to the written public comment of Jonathan Dennis on behalf of the Psychedelic Bar Association. *See* DOH Exhibit No. 10 at pages 5 - 6. First, the Department address Mr. Dennis's comments on the intersection of medical and religious use. The Department echoes Mr. Dennis's comment that the Medical Psilocybin Act makes no reference to religious use, and states that the DOH is not authorized in the MPA to enroll individuals in the Program for religious use of psilocybin. Thus, the Department states that it is not within the legal role of the Department to enroll persons for the religious use of psilocybin.

The Department then comments on Mr. Dennis's comments regarding sale restrictions and federal tax consequences. The Department took issue with Mr. Dennis's recommendation to allow

direct sales from producers to patients in order to reduce the impact of Section 280(E) from the IRS Code. The Department asserts that allowing direct sales from producers to patients would encourage self-dosing and recreational use. The Department is committed to ensuring that producers of psilocybin products only distribute those products to clinicians, and ensuring that the administration of psilocybin only occurs in supervised clinical settings. The Department notes that medical psilocybin presents unique health risks and in that way is very different from medical cannabis. Further, the MPA at NMSA 1978 §§ 26-2D-1 through 11, emphasizes the involvement of clinicians and the ingestion of psilocybin only in supervised administration sessions as part of an integrated therapeutic practice. The Department asserts that its approach in the proposed new rule is consistent with that legislative intent.

The Department then addresses Mr. Dennis's comments regarding anticipating and reducing negative consequences of profit motives. The Department notes that Mr. Dennis highlighted the proposed requirement that permittee investors "enjoy the customary incidents of ownership," and recommended that the rule clarify that passive investments are allowed within the program. The Department states in response that it believes that the proposed text of the rule, as revised in the response to public comments and as set for in the List of Anticipated Revisions (DOH Exhibit No. 8) is appropriate. The Department asserts that requiring that investors enjoy the customary incidents of ownership proportionate to their percentage of ownership is not unduly burdensome and will help to ensure that permittees do not enter straw-man type arrangements in which actual control of a permittee is vested in persons other than those who hold record ownership of the company.

Finally, the Department responds to Mr. Dennis's comments regarding restrictors for property-renting applicants. The Department states that Mr. Dennis proposed that the rule not require that a permit applicant submit an attestation form from a landlord acknowledging that the property will be used for the purpose of cultivating psilocybin. Mr. Dennis raised concern that such an attestation could expose a landlord to civil and criminal liability, thereby making landlords reluctant to provide such an attestation. Mr. Dennis proposed a "lease agreement pathway," and the scope of any written approval should be limited to only requiring permission to participate in a DOH-licensed program.

The Department responds by stating 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, given the state of federal law and the potential for negative legal repercussions for landlords (such as property seizures), including those landlords may not be aware of such activities occurring on the premises. The Department notes that in response to such comments, it proposes to modify the text of subsection 7.35.2.8(A) NMAC as set forth in the List of Anticipated Revisions. *See* DOH Exhibit No. 8.

In its written response to written public comments, the Department also commented on the written public comments of Gregory Evans. *See* DOH Exhibit No. 10 at pages 1 - 4, as follows:

The Department agrees that a definition of "certificate of analysis" should be added to 7.35.2.7 NMAC but it prefers the following 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."

The Department agrees with Mr. Evan's recommendation that a maximum water content of 10% be added to 7.35.3.19(F) NMAC.

The Department agrees with Mr. Evan's recommendation to add the term "cultivation batch" to 7.35.2.10(A)(6) NMAC.

The Department states that the requested phrase "harvest lot" was added to 7.35.2.15(A)(1) NMAC prior to the rule hearing. [The phrase "harvest lots" does appear in 7.35.2.15(A) NMAC, but not in subsection (A)(1), where Mr. Evans proposes it should be added.]

The Department does not agree to Mr. Evans recommendation that the definition of "inoculate" in 7.35.2.7(I)(2) NMAC is biologically inaccurate because spores do not contain psilocybin and the definition refers to "psilocybin spores." The Department states that it understands that spores do not contain psilocybin. The Department explains that "psilocybin spores" in the definition refers to spores that produce a mushroom containing psilocybin. The Department states that adding to the definition of "inoculate" would be beneficial.

Mr. Evans asserts that the bundled compound in the definition of "psilocybin" in 7.35.2.7(P)(10) NMAC creates regulatory ambiguity. The Department responds by stating that the definition in the proposed rule is identical to the statutory definition of "psilocybin" in NMSA 1978, § 26-2D-3(G), and, thus, should not be altered.

Mr. Evans asserts that the definitions of "cultivation" and "manufacture" in 7.35.2.7(C)(7) and (M)(1) NMAC have overlapping scope and create conflicting obligations, as well as preventing the assignment of unique identification numbers for each stage. The Department asserts 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.

Mr. Evans states that the level of analytes in the definition of "potency" in 7.35.2.7(P)(6) NMAC is unspecified and two labs testing the same sample could report different analyte panels. The Department responds by stating that potency testing and required analytes are specified in the rule at 7.35.2.19(G) NMAC and the rule sets the reporting measurements in milligrams/gm, which is a metric unit.

Mr. Evans recommends removing the species constraint in the definition of "mycelium" in 7.35.2.7(M)(3) NMAC so that the rule can reference "mycelium" accurately in any context. The Department asserts that the definition is sufficiently accurate 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.

Mr. Evans asserts that the definition of "fruiting bodies" in 7.35.2.7(F)(3) NMAC is scientifically inaccurate and also reduces the fruiting body to a single function, rather than the material harvested, dried, tested, and administered under this rule. The Department states that the

definition is sufficiently accurate for the Program's purposes, and that adding the words "including associated structures" might be technically more specific, but would not add clarity or needed meaning to the definition.

Mr. Evans asserts that 7.35.2.15(A) NMCA requires producers to track cultivation batches, harvest lots, homogenized lots, product lots, and psilocybin product inventory. He further states that 7.35.2.15(A)(1) NMAC assigns UIDs to cultivation batches, homogenized lots, and product lots, and the definitions do not connect the states to one another; as he puts it—the chain is broken. Mr. Evans asserts that his proposed, amended definitions of "cultivation," "harvest lot," "homogenized lot," and "product lot" chain each stage to its parent, constrain genetic origin, require homogenization, specify product, and resolve a Subsections 7.35.2.10(A)(6) and 15(A)(1) UID inconsistency at the definitional level.

The Department responds to the foregoing concerns by stating that in order 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. The Department states that the definitions are accurate, and can be followed by producers without confusion.

Mr. Evans asserts that 7.35.2.7(C)(8) NMAC, the definition of "cultivation batch" allows for mixed genetic origin. He further asserts that homogenization is not required because 7.35.7.2(H)(5) NMAC, the definition of "homogenized lot," does not refer to 7.35.7.2(H)(4), the definition of "homogenized." In addition, he argues that the phrase "same type of product" in the definition of "product lot" in 7.35.2.7(P)(8) NMAC is undefined, making the definition of "product lot" underspecified.

The Department responds by stating that the language of the foregoing regulations was intentional to allow producers to grow multiple species of psilocybin-containing mushrooms that may vary in psilocybin content. The Department further notes that testing of the finished product will determine the important parameter of the amount of psilocybin contained in the product. The Department also believes that adding the term "powder" to the definition of "homogenized lot," when the definition of "homogenized" requires "powdering" would be redundant and unnecessary.

Mr. Evans further states that the UID lists are inconsistent because 7.35.2.10(A)(6) NMAC lists harvest lots, homogenized lots, and product lots, and 7.35.2.15(A)(1) NMAC lists cultivation batch, homogenized lots, and product lots. The Department agrees that "cultivation batch" should be added to Subsection 7.35.2.10(A)(6).

Mr. Evans states that 7.35.2.7(H)(5) NMAC has a "dead clause" because it includes the phrase "harvested within a specified time period" and has no value assigned. The Department is satisfied with the current definition, and believes that Mr. Evans' proposed longer and more complex definition would not reduce confusion or add meaningful information. The Department asserts that the lack of a time value was intentional, to allow for the producer to self-determine the time period, based on business practice and different growth time for different type of psilocybin-containing mushrooms.

Mr. Evans asserts that the phrase "may include" (referring to cultivation batches, harvest lots, homogenized lots, product lots, and testing samples) in the definition of "UID" at 7.35.2.7(U) NMAC makes UID coverage permissive, and a producer cannot tell whether UID assignment at any given stage is required or optional. The Department responds that the words "may include" do not grant permission to ignore assigning a UID to each stage as defined.

Mr. Evans recommends that a definition of the word "spawn" (which appears in his recommended amendment to the definition of "inoculate"), be added to the rule. He asserts that this addition anchors the definition of "inoculate" and supports 7.35.2.12(C) NMAC and 7.35.2.15 NMAC traceability, and aligns with the batch definition's origin constraint. The Department states that adding a definition for the word "spawn" would not add meaningful content to the rule, and notes that spawn arise from germinating spores and are not a separate biological entity.

Mr. Evans argues that rule 7.35.2.14(A)(4)(j) NMAC requires and expiration date on every label, and rule 7.35.2.7(E) NMAC defines expiration date but the rule never defines how a producer determines that date. He argues that there is no shelf-life definition; no stability testing requirement; and no methodology. He argues that addressing these issues would anchor shelf life to homogenization, labeled potency, and producer-specific storage conditions. He further asserts that a twelve-month ceiling on the product reflects the board's adopted framework.

The Department responds that it was not defined a shelf life or expiration date for psilocybin product because there is little scientific information regarding the stability of homogenized powdered psilocybin mushrooms. The Department further asserts that 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. The Department states that this study found some degradation of psilocybin beginning at one month even under the best storage conditions, and a more pronounced drop between two and 15 months. In addition, the Department refers to a study from Rose City Labs, which found conversion of psilocybin with a small decrease in potency after three months of storage.

The Department asserts that, 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. It notes that as it gains experience with the results of testing, the rules allow for changing testing frequency.

Mr. Evans identified eight definitions in 7.35.2.7 NMAC in which the operative scope falls outside the proposed regulations. *See* Mr. Evans' Items 13 through 20 on page 6 of his Public Comment on Proposed Rule 7.35.2 NMAC in DOH Exhibit No. 9. He argues that these terms should be finalized in the appropriate committee's rulemaking process, not in this 7.35.2 NMAC rulemaking process.

The Department responds that it has proposed adopting certain definitions in the rule that are particular to psilocybin patients and practitioners, and notes that some of those terms are not used at all outside the definitions. The Department states that it 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. It notes that if those definitions are determined to require revisions in the future, they can be amended at that time.

Mr. Evans proposes a new provision that focuses on water activity. He argues that 7.35.2.19(E) NMAC requires testing of organisms on finished product but does not regulate the moisture condition enabling growth. He argues that below 0.6 aw no pathogen, yeast, or mold relevant to this matrix can grow. He further states that Subsection 7.35.2.19(F) measures total moisture, and water activity measures the fraction available to biology. He argues both are needed.

The Department responds by stating that it believes that adding a subsection related to water activity would be redundant and unnecessary because a water content of 10% is generally analogous to a water activity of the proposed 0.6 aw. The Department further states that 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. In addition, the Department notes that this is part of the reason why the Department has proposed to require additional testing for contaminants.

Mr. Evans also proposes to reduce the microbes listed for testing in Table 1 of 7.35.2.19(E) NMAC ("Microbial testing") to four specified microbes, rather than the nine microbes listed by the Department in the proposed rule. The Department responds by stating that it believes that testing for each of the required microbial species is reasonable and appropriate. The Department states that the medical conditions that qualify a patient for enrollment in the Program often come with co-morbidities, (including immunosuppression,) which require pathogen-free mushroom products. The Department notes that each required species to be tested can cause serious illness or death in patients who are immunocompromised or seriously ill.

In addition, the Department states that the testing panel was created after consultation with the American Herbal Products Association, the USDA, the National Advisory Committee on Microbial Criteria in Foods, review of the Oregon and Colorado Psilocybin program requirements, and discussion with psilocybin testing labs in Colorado, Oregon, and Florida.

The Department states that it also is concerned that the Program may attract novice producer entrants with varying skill levels; it finds that more thorough testing at the start will better ensure the safety of patients. It states that with more experience with testing results, the Department may adjust the testing frequency requirements through rulemaking.

Mr. Evans argues that a retest cadence appears in four subsections of the produced rule, each restating the same interval independently. He argues that a single policy change requires four amendments. The Department responds that it believes that referencing the re-test cadence in four passages of Section 7.35.3.19 in not problematic, and it serves a useful purpose, as each reference relates to the testing of different analyses.

Mr. Evans asserts that Subsection 7.35.2.19(B)(1) caps samples at 1 - 5 grams for every 1 kilogram and defers to lab sampling protocols in the same sentence. He argues that a validated method requiring more than 5 grams has "nowhere to land." The Department argues that, having consulted with laboratories in Colorado and Oregon, it believes that a sample size of 1 - 5 grams

will be sufficient for all testing, and give producers notice of the amount of product that they can expect to lose in the course of testing; the Department asserts that these amount should be in line with laboratory standard operating procedures.

Mr. Evans states that Section 7.35.2.11 authorizes capsules, sachets, and homogenized dried powder, but no provision authorizes solvent-based extraction or concentration. He recommends striking solvent references from Subsections 10(A)(2), 13, 20(B), and 21(A). He would replace the with cleaning-agent language where applicable. He states that if the Department later authorizes extracted product forms, solvent controls would attach to that authorization.

Mr. Evans asserts that Subsection 7.35.2.14(A)(4)(h) requires two calculated values for potency calculation but the rule omits conversion factor, analyte inputs, and calculation formula. He asserts that two laboratories testing identical sample could report different label values. He states that potency calculation is a technical standard that belongs in a standard operating approval process, where it can be validated, standardized and updated without a rule amendment. He asserts that every permitted lab uses the same formula.

The Department responds that it believes that it is unnecessary to include conversion factors, analyte inputs, and calculation formulas in the rule, because these parameters have been standardized via accepted standardized operating procedures for testing laboratories.

The Department's List of Anticipated Revisions to 7.35.2 NMAC

The Department generated its written List of Anticipated Revisions to 7.35.2 NMAC prior to the hearing on April 24, 2026. *See* DOH Exhibit No. 8. The DOH proposed the revisions to the proposed rule (DOH Exhibit No. 2) at the time of hearing in the comments of Dominick Zurlo. The proposed amendments include a revision to the definition of "actual control," at 7.35.2.7(A)(1) NMAC, 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.

The Department states that the foregoing revisions are designed 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 to any one person. By removing the "exert authority" test 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. The revision was also intended to ensure that the definition of "actual control" does not conflict with the "genuine ownership" requirements of 7.35.2.9(B) NMAC, which, the Department states, 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's proposed revisions to the rule include a revised definition of "administration session" in 7.35.2.7(A)(2) as follows:

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

The Department states that this revision of the definition 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.

The Department proposes to revise the following definition to correct a mistaken word choice:7.35.3.7(I)(2) NMAC: "Inoculate" means the process of introducing psilocybin spores [~~of~~] or mycelium into growth medium.

The Department proposes to revise the application submittal requirements concerning rental properties in 7.35.2.8(A) NMAC as follows:

> 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 psyilocybin products will be produced or tested on the premises.

The Department states that this revision is meant to substitute a written acknowledgement from the property owner for the previously proposed "approval" from the owner.

The Department proposes revising the rule regarding the restriction on transferability of permits found in 7.35.2.9(C) NMAC as follows:

> 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.

The Department states that this revision is designed to create an exception to the general prohibition against the transfer of permits in the limited circumstance where a permittee who is a sole proprietor dies. In this situation , they only way the entity could survive and continue operation is through a transfer of the permit in its entirety.

The Department proposes a revision to 7.35.2.19(E) NMAC, "Total Yeast and Molds" Action Level from >20CFU to >1,000 CF, based on the recommended limit set by the American Herbal Products Association for yeasts and molds in powdered dried food products.

The Department proposes a revision to 7.35.2.19(F) NMAC to specify that "Water content shall be less than 10%" in order to pass water content testing. The Department states that 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; the Department believes a 10% cap is reasonable and will suffice to reduce bacterial growth.

The Department proposes to revise 7.35.2.26(B) to specify that a courtesy copy of a notice 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. The Department states that this was meant to be included in the proposed rule, but was accidentally omitted.

Finally, in its List of Anticipated Revisions, the Department states that it proposes to revise 7.35.2.19 NMAC Table 4 to modify certain pesticide testing action levels as follows:

- Abamectin from level 0.01 to 0.15;
- Bifenthrin from level 0.05 to 0.1; and
- Metrafenone from level 0.05 to 0.5.

The Department states that these three revisions are necessary to correct typographical errors and more closely reflect relevant standards used for cannabis testing.

Analysis and Recommendation

In conducting the analysis of the issues in this rule promulgation process, the Hearing Officer was guided by New Mexico case law which provides instruction in determining whether a rule adopted by an administrative agency will be upheld. This guidance can be found in *New Mexico Mining Association v. New Mexico Mining Commission,* 1996-NMCA-098, 122 N.M. 332 at ¶ 15, which states as follows:

> Rules adopted by an administrative agency will be upheld if they are in harmony with the agency's express statutory authority or spring from those powers that may be fairly implied therefrom. [Citations omitted.] Similarly, regulations adopted by an agency are presumed to be valid if they are shown to be reasonably consistent with the statutory purposes of the agency. [Citation omitted.]

See also Rio Grande Chapter of Sierra Club v. New Mexico Mining Comm'n, 2003-NMSC-005, 133 N.M. 97 at ¶25.

The Hearing Officer has reviewed the exhibits and the public comments at hearing regarding the proposed new rule 7.35.2 NMAC. Further, the Hearing Officer has reviewed the New Mexico Psilocybin Act, giving a particular focus to NMSA 1978, §26-2D-7(A) from the New Mexico Medical Psilocybin Act, which states as follows:

> A. The "medical use of psilocybin program" is created in the department. In developing the program, the department shall establish:
>
> (1) appropriate qualifying conditions for qualified patients;
>
> (2) necessary initial and ongoing training for producers and clinicians;

(3) treatment protocols, including patient selection criteria, medical service standards, dosage standards and approved settings for administration of psilocybin to patients;

(4) safety protocols for producing psilocybin from mushrooms, transporting, storing and handling psilocybin and treating patients;

(5) other best practices for producers and clinicians;

(6) requirements for data collection to evaluate the program and the use of best practices by producers and clinicians; and

(7) other requirements, restrictions and limitations promulgated by the department to ensure an efficacious program.

The provisions outlined in the foregoing statute give the Department broad authority to establish the Medical Psilocybin Program and to establish the rules that govern it. Extensive public comments were provided to the Department in this rule promulgation process. The written response of the Department to those comments indicates that this has been a thorough rulemaking process, and that the Department has given careful consideration to the development of the new rule, the input from the public regarding the new rule, and a willingness to amend the proposed rule even prior to its final adoption. The Department has made the effort to consider the psilocybin programs of other states—Oregon and Colorado—and consulted with professional organizations such as American Herbal Products Association, and the National Advisory Committee on Microbiological Criteria. The Department has also consulted with the USDA. Further, it has consulted scientific studies, such as the "Stability of psilocybin and its four analogs in the biomass of the psychotropic mushroom Psilocybin cubensis," by Gotvaldova, Hajkova, et al.

The Department has, as indicated above, submitted a written List of Anticipated Revisions, which arose out of comments from the public. It has also indicated in its written response to public comments that it intends to make further revisions to the proposed rules based upon the comments received from the public. It has also indicated that comments from the public may result in new rules or newly amended rules in the future.

The May 13, 2026 written response to public comments that was submitted to the Department supports the conclusion that the Department made the effort to consider the recommendations of the public with care and attention, as well as a willingness to adopt the recommendations that were made by the public where appropriate. The Hearing Officer adopts the responses of the Department to public comment, and, consequently, incorporates them into this Analysis.

The provisions found in the new rule, with the amendments found in the List of Anticipated Revisions, and in the May 13, 2026 written response of the Department, are consistent with the requirements of the foregoing statute. The Hearing Officer recommends that the Cabinet Secretary find that the proposed new rule, with amendments, is consistent with the authority granted to the agency in rulemaking and consistent with the statutory purposes of the agency set forth in the

statute. The proposed new rule is in harmony with the agency's express statutory authority or spring from those powers that may be fairly implied therefrom. *See New Mexico Mining Association v. New Mexico Mining Commission,* 1996-NMCA-098, 122 N.M. 332 at ¶ 15. The Hearing Officer, having reviewed the record in this proceeding in full, recommends that the Secretary find that the provisions of the proposed new rule 7.35.2 NMAC are in harmony with, and/or spring from the authority given to the Department under the relevant statutes.

Recommendations

Based upon the foregoing, the Hearing Officer recommends that the Secretary adopt the proposed new rule 7.35.2 NMAC ("Medical Psilocybin Producer and Laboratory Requirements") by the Department, as set forth in DOH Exhibit No. 2, together with the amendments to the proposed rule found in the List of Anticipated Revisions (DOH Exhibit No. 8), and the amendments found in the Department's Written Response to Public Comments (DOH Exhibit No. 10.)

Original Signed by Craig T. Erickson on 5/26/26

Craig T. Erickson
Hearing Officer

Date