Via E-Mail

November 9, 2026

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

Re: Public Comments in Rulemaking for 7.35.3 NMAC, Medical Psilocybin (Patient and Practitioner Rule)

Dear Mr. Erickson:

The New Mexico Department of Health offers the following responses to substantive proposals made in the public comments submitted during the rulemaking proceeding for the proposed new rule 7.35.3 NMAC, Medical Psilocybin; Patients, Certifying Clinicians, Practitioners, Facilitators, Healing Centers, Other Approved Locations, and Educational Programs. Due to the substantial volume of comments received, the Department has organized the following by topic, consolidating related comments and the Department's position under each heading.

1. Patient Application and Enrollment

Several commenters objected to the patient-application framework, including the proposed 30-day Department review period, and argued that a registration process modeled on the Medical Cannabis Program is unnecessary for a supervised, private psilocybin program that issues no patient cards.

The Medical Psilocybin Act at NMSA 1978, § 26-2D-9 requires that the Department of Health adopt rules "for the collection of data from producers, clinicians *and qualified patients*" to evaluate the efficacy of the medical use of psilocybin and publish an annual assessment of the program. NMSA 1978, § 26-2D-9. While that section requires that data be reported in such a way that an individual qualified patient cannot be identified, that requirement refers to the Department's reporting of information concerning patients, rather than to its collection of data.

The patient enrollment process is not intended to be an involved process, and does not require the Department to render any clinical decisions regarding individual patients, or to collect detailed clinical records. Rather, it is a straightforward enrollment process that collects basic information about patients who will participate in the program.

In consideration of the comments received, the Department proposes to reduce the 30-calendar-day maximum processing period at section 8(C) to 10 business days; will revise references to "applicant" to specify "patient"; and will include text to clarify that this is an enrollment process, rather than a more involved "application process".

2. Certifying Clinician Qualifications and the Certification Gateway

Some commenters objected to the clinician-centered model of the rule generally, as well as the specific requirement that a certifying clinician serve as the gateway to the program, and the requirement that a certifying clinician hold a New Mexico controlled-substance registration. Some commenters proposed that the Department instead adopt a medical screening and referral model that requires providers to utilize a screening tool to refer patients to medical providers if they have contraindicated conditions.

The statute at NMSA 1978, § 26-2D-3(H) defines "qualified patient" as "a patient whose clinician has judged the patient to be a medically appropriate candidate for the use of medical psilocybin based on being diagnosed with a qualifying condition". As such, a patient must be certified by a clinician in order to be enrolled in the program.

However, the Department understands the concerns regarding access that were raised by commenters. Based on the comments received, the Department proposes to remove references to the "certifying clinician" from the rule, and instead rely on practitioner screening and referral of patients who have contraindicated conditions or treatments. (Note that a "practitioner" is defined in the proposed rule as a type of clinician certified by the Department, and practitioner certification therefore comports with the statutory requirement described above.) Contraindicated conditions and treatments to be listed in the rule will include:

- Cardiovascular disease;
- Seizure disorder or history of seizure;
- Moderate or greater head trauma;
- Hypertension;
- History of stroke or cerebrovascular disease, including but not limited to aneurysms;
- Asthma/ COPD;
- Diabetes;
- Psychosis or disease with a risk of psychosis (including bipolar disorder);
- Medication/drug-interaction contraindications (such as lithium, and drugs with serotonergic/psychotropic interactions);
- History of suicide attempt, thoughts of self-harm, or thoughts of harming others;
- Use of medical devices including but not limited to insulin pump, continuous glucose sensor feeding tubes, ostomies, central lines, supplemental oxygen, dialysis, tracheostomy, pacemaker, external defibrillators, pain pump, stimulators or other implantable device; and
- Such additional contraindicated conditions or treatments as the Department may require.

Requirements concerning certifying clinicians at section 7.35.3.18(B) NMAC will be deleted, along with continuing education requirements for certifying clinicians.

The provider who certifies the patient will not be required to hold a controlled substances registration.

Section 8(B) will be revised to require that the practitioner attest:

- that the practitioner has completed the required department screening tool;
- that the practitioner has referred the patient to a medical provider (with the appropriate scope of practice to evaluate potential medical risk) if either:

  1) there are medical risks indicated through the screening tool review,
  2) the patient has not seen a medical provider within the previous 12 months; or
  3) the practitioner has otherwise chosen, within the practitioner's discretion, to make the referral.

The practitioner will also be required to attest that the practitioner has determined, in their professional opinion and based on consultation with the medical provider (as applicable) that:

1) the potential health benefits of the medical use of psilocybin likely outweigh the health risks for the patient; and

2) there are no identified medical risks that cannot be adequately addressed during treatment; or to the extent that there are any identified medical risks, a written plan has been created to address those risks during treatment, which will be implemented by the treating practitioner.

3. In-Person Examination, Telehealth, and Pre-Administration Screening; VA Certifier Barrier

Some commenters objected that the requirement that there be an in-person examination by a certifying clinician burdens rural patients, raises costs, and is unnecessary, and they asked that telehealth evaluation be permitted and that end-of-life patients be accommodated. Related comments proposed that an initial screening (inquiry into medical and mental conditions and medications) replace a mandatory physical examination, with medical clearance required only where screening identifies an issue. Commenters also stated concern that patients who are seen by Veterans Administration healthcare providers would have greater obstacles meeting the certification requirements, since their providers (as federal employees) would be prohibited from certifying patients for the use of psilocybin, which is a Schedule I drug under federal drug laws.

As noted, the Department intends to remove the "certifying clinician" provisions of the rule, including the in-person examination requirement at section 13(A), in favor of allowing practitioners to certify patients based on the above-described medical screening process.

Rather than requiring that a certifying clinician conduct an in-person examination within the previous six months, the Department intends to incorporate a requirement within section 8(B) that patients who have not been seen by a medical provider in the previous 12 months be referred to a medical provider before being certified to the program. This will effectively remove the requirement that every examination be in-person. This screening process will be more individual-specific and should be less burdensome for patients in the program.

4. Treatment Locations and Settings

Commenters raised several issues concerning where treatment may occur, including the landlord-attestation requirement, its interaction with federally assisted housing, the enumerated list of other approved locations, the 90-day certification period for such locations, and treatment at long-term care facilities.

a. Landlord/Property-Owner Statement

The Department received considerable public comment regarding the proposed requirements at sections 11(A) and (B), which would require that an attestation be obtained from a landlord or property owner as a precondition of approval of a healing center or an "other approved location". In consideration of the comments received, the Department intends to strike the landlord/property-owner statement requirements and will replace them with a requirement that the applicant attest that they are the owner of the property or that they are aware of the legal risk concerning the property. The Department will offer educational material to patients regarding the potential consequences of psilocybin use, and will also include a requirement within section 8 that the patient attest that they have been informed of the legal status of psilocybin and potential consequences of using it.

Psilocybin is classified as a Schedule I drug under federal drug laws, the possession of which is deemed federally illegal, which may (in some circumstances) result in forfeiture of property associated with its possession. In adopting these provisions, the Department seeks to ensure that applicants for healing centers and other approved locations, and patients, are enabled to make informed decisions.

b. Federally Assisted Housing

Comments regarding potential conflicts with Section 8 / federally assisted housing are effectively resolved by the removal of the landlord-approval requirement, described above.

c. Enumerated List of Other Approved Locations

One commenter observed that, because section 7.35.3.11(B) lists specific reasons for certifying other locations, any reason not listed might be presumed excluded, and recommended a catch-all provision. The Department declines to modify the provision; the existing language is broad enough to meet the anticipated needs for approval of other locations.

d. 90-Day Certification Period

A commenter objected that other approved locations, intended to improve rural and frontier access, require a lengthy application yet expire after only 90 days, and recommended matching the certification to the patient's enrollment period. The Department declines to change this. The certification of "other approved locations" is intended to allow temporary (not extended) use.

e. Long-Term Care Facilities

One commenter emphasized that treatment should be available at long-term care facilities. The proposed rules do not prohibit treatment at long-term care facilities. It would be for such a facility to decide whether to apply to become an approved location.

5. Staffing Ratios, Practitioners, and Facilitators

Commenters addressed the session staffing requirements, the eligibility of certain licensed professionals to serve as practitioners, and the liability implications of practitioner supervision of facilitators.

a. Staffing Ratios

Some commenters requested that the Department increase the ratio of patients to practitioners and facilitators during administration sessions. In consideration of the comments received on this topic, the Department proposes to make the following revisions to the staffing ratios at section 20(H):

For individual patient sessions, a minimum of one practitioner and one *additional practitioner or facilitator* will be present.

For group sessions, the ratio will be modified to allow one practitioner for every *nine* patients and at least one *additional practitioner*, facilitator, or qualified student for every *three* patients.
For example, if there are three patients, there must be a minimum of two practitioners/facilitators; if there are 6 patients, it would be one practitioner and two additional practitioner/facilitators; if there are 9 patients, it would be one practitioner and three additional practitioner/facilitators; if there are 10 patients, it would be two practitioners and 4 additional practitioner facilitators.

The text of this section will be revised to clarify that, for purposes of being "present" during an administration session, the practitioner will only need to be in the building (i.e., within range to be called into the room in case of an emergency), not necessarily present in the administration session itself. The concern here is that facilitators are not licensed medical professionals and are not necessarily qualified to address emergency medical/therapeutic episodes. These ratios are intended for safety reasons, and to ensure patients get the attention needed during their administration and journey.

b. Practitioner Eligibility

The Department received a comment asking whether a given practitioner license would be eligible for practitioner certification in the program. To clarify which practitioners may be certified in the program, the Department proposes to add text at section 9(E)(1) that specifies examples of licensed providers who hold professional licensure in NM to practice therapy, counseling, or behavioral services, consisting of licensed therapists, licensed professional clinical counselors, licensed mental health counselors, licensed alcohol and drug abuse counselors, licensed independent social workers, licensed clinical social workers, licensed master social workers, licensed psychologists,

psychiatrists, psychiatric nurse practitioners, and advanced practice registered nurses. This passage will include a catch-all provision that authorizes a person whose license does not fall within this list to submit a letter from their licensing body indicating that utilization of medical psilocybin is within their professional scope of practice.

c. Supervision and Malpractice Exposure

Some commenters expressed concern that placing a non-licensed facilitator under a practitioner's supervision could extend the practitioner's malpractice exposure to the facilitator while leaving the facilitator outside the corresponding coverage framework, and recommended treating the two roles as independent.

In response, the Department notes that the "facilitator" designation is a creation of this rule, and does not exist in the Medical Psilocybin Act: the only providers referenced in the statute are "clinicians". For this reason, it is the Department's position that facilitators cannot lawfully operate within the program without clinician supervision, because their ability to function within the program effectively derives from clinicians.

It is also the understanding of the Department that most facilitators in Oregon and Colorado (whose state laws also legalize psilocybin usage) carry liability policies for protection against malpractice, and that there are in fact insurance carriers willing to insure facilitators.

d. Rural Wilderness Staffing

One commenter suggested that the requirement at section 20(K), that there be at least two individuals present during administration sessions who have wilderness first aid certification, wilderness first responder certification, or licensure as a New Mexico emergency medical technician, is too costly, and that one person would be sufficient. The Department disagrees. This is not an unusual safety precaution for experiences in wilderness areas. For example, Scouting America requires any group participating in treks at the Philmont Scout Ranch in New Mexico have two members who are trained in Wilderness First Aid. (https://www.scouting.org/health-and-safety/safety-moments/wilderness-first-aid/)

6. Training and Education Requirements

Commenters raised several training and curriculum issues, including the overall practicum burden, specific content gaps, an internal inconsistency in the practicum-reciprocity provisions, the accuracy of references to Native use, touch-consent instruction, third-party curriculum evaluation, and a numbering error.

a. Practicum Burden

Some commenters recommended that the practicum requirements be reduced; the Department declines to do so. The Department notes that the practicum hours were previously increased in response to earlier public input, and the Department does not believe that further revisions would be beneficial.

b. Content Gaps

Some commenters sought express coverage within the training requirements for suicidality, challenging experiences, trauma, end-of-life care, and pharmacology. The Department notes that most of these subjects are already encompassed within existing curriculum requirements. For example, pharmacology (7.35.3.18(C)(1)(g)), trauma (7.35.3.18(C)(1)(c)), clinical research (7.35.3.18(v)), end-of-life care (within "education on the qualifying conditions and appropriate treatment practices," 7.35.3.18(C)(1)(o)), and "bad trips and medical emergencies" (addressed as "psychedelic emergencies, urgencies, complications, and medical monitoring," 7.35.3.18(C)(1)(d)) are all addressed within the rule as proposed. For additional clarity, the Department proposes to add the term "suicidality response" to 7.35.3.18(C)(1)(e) NMAC. The Department declines to prescribe fixed hours for individual topics, considering that topic length may change, and the rule should allow educational programs to make adjustments without requiring a rule change.

c. Practicum-Reciprocity Inconsistency

Commenters correctly identified a conflict between section 7.35.3.10(D)(1) (40 hours, two individual and two group sessions) and section 7.35.3.19(H)(4)(b) (40 hours, two individual and one group session). This was a continuity/typographic error. The Department proposes to revise both sections to read "one group session." The Department intends to retain the requirement of experience across more than one modality, as experience in only one modality would not demonstrate the flexibility and expertise required through the primary certification process.

d. References to Traditional Use by Native Americans

One commenter noted an absence of evidence of traditional psilocybin use by peoples indigenous to New Mexico. The Department has adjusted the language to require training on the "historical aspects of psychedelic use, including traditional use by Native American and other populations in New Mexico."

e. Touch and Consent

Commenters recommended that the curriculum expressly address touch consent and that the Department define permissible and prohibited touch. Somatic training is already included in the proposed regulations (7.35.3.18(C)(y)), and informed consent is already a required training topic (7.35.3.18(C)(1)(x)). The Department declines to promulgate rules defining permissible touch, as this is a negotiated patient-provider boundary addressed through training rather than a matter for specification in DOH rule.

f. Third-Party Curriculum Evaluation

One commenter questioned the rigor of allowing training programs to assemble their own evaluation panels and asked how the rule intersects with New Mexico Higher Education Department (HED) regulations. However, the Department is not requiring educational programs

to comply with HED regulations; it is requiring programs to undergo a formal evaluation of their curriculum and program.

g. Practicum with Other Students

One commenter requested that practicum students be permitted to train on one another rather than with qualifying patients. The Department cannot lawfully adopt this recommendation, due to the fact that psilocybin consumption by non-patients is illegal under NM state law. Unlike Colorado, New Mexico has not legalized psilocybin consumption generally, and students therefore could not lawfully consume psilocybin in the course of training.

h. Numbering

The Department will correct the faulty numbering of 7.35.3.12(A), items 21–24, which is a typographic error.

7. Cost, Affordability, and Microdosing

Commenters raised concerns about program affordability, citing supervision costs, training costs, treatment-room costs, and testing costs, and compared prices in Oregon. Some commenters proposed a microdosing pathway as a lower-cost option.

The Department is unable to make a full determination regarding cost and affordability until more information is available on what providers will charge, and any present estimate would be speculative. The Department also lacks authority to restrict or set practitioner fees.

The Department notes, however, that the revised rule permits students who have completed half of their practicum to be counted toward the provider-patient ratio, and the Department is proposing to adjust group staffing ratios (as described above), both of which should reduce costs below the figures cited by commenters. Additionally, the Department does not intend to charge a fee for permits, certificates, or applications, which should help to alleviate costs for permitted and certified persons and entities.

Regarding microdosing: the Department appreciates the interest, but believes that microdosing would be more of a clinical consideration for providers than a structural feature of the program. Microdosing is not prohibited by the existing framework where the practitioner and patient agree to use low doses, provided that administration occurs in the approved settings as required by statute. *See* NMSA 1978, § 26-2D-7(A)(3) (requiring the Department to establish treatment protocols that include "approved settings for administration of psilocybin to patients").

8. Ownership and Vertical Integration

One commenter urged that clinicians be permitted to grow the medicine they prescribe and to vertically integrate prescribing, cultivation, and administration, arguing this would substantially reduce costs.

The Department declines to adopt vertical integration in the cultivation and administration of psilocybin. Such a model would create the very conflicts of interest the Department seeks to avoid. For example, where a provider is also the producer, the provider would both sell and produce the product, creating an incentive to sell more product than the patient needs, to raise prices to improve the provider's bottom line, or to bypass safety requirements such as product testing.

There is also no indication that a vertically integrated model would necessarily reduce costs, as the same production requirements would apply. In fact, it could actually increase costs by multiplying production locations and thereby increasing statewide expenditures on electricity, water, travel for testing, and build-out, as well as the Department's regulatory oversight burden. A defined set of production locations should yield lower overall statewide production and oversight costs.

9. Confidentiality and Justice-Involved Patients

One commenter requested that the Department specify in the rule that justice-system involvement does not disqualify an otherwise qualified patient, that participation must be voluntary (though a court or probation referral does not render it involuntary), and that declining treatment carries no adverse consequence; the commenter also sought guidance on 42 CFR Part 2, HIPAA, and state confidentiality requirements.

The statute at NMSA 1978, § 26-2D-10 provides that a person serving probation or parole, or in custody or under supervision pending trial as part of a community supervision program, shall not be penalized for participation in the program. Because that protection exists in statute, it need not be repeated in the rule.

The Department lacks authority over courts, probation departments, diversion programs, and community supervision programs, and generally cannot dictate their requirements through rule.

10. Appeals and Due Process

Some commenters objected that the appeals process (section 7.35.3.27) is inaccessible, requiring hearing requests by certified mail and in-person hearings in Santa Fe, and questioned the allocation of the burden of proof.

a. Accessibility

The Department declines to modify the certified-mail and venue provisions. Section 7.35.3.27(D) requires that a hearing request be sent by certified mail, and section 7.35.3.27(E) provides that hearings are held in Santa Fe, except that where the appellant lives more than 100 miles from Santa Fe, or the parties agree, the hearing may be conducted by telephone or web video. These standards are not unduly onerous, and the rule leaves open the possibility of a web-based hearing in every case.

b. Burden of Proof

Section 7.35.3.27(L), as proposed, would place the burden on the appellant to establish by a preponderance of the evidence that the Department's decision should be reversed or modified. In consideration of the comments received on this topic, the Department proposes to revise this provision to specify that the appellant bears the burden where the Department has denied an initial application, whereas the Department bears the burden when it has suspended or revoked an existing certificate. Whereas an existing certificate may implicate due-process interests of the holder, the same is not true of the denial of an initial application (*see, e.g., New Mexico State Racing Comm'n v. Yoakum*, 1991-NMCA-153, 113 N.M. 561); and it is a familiar practice for licensing and certifying bodies to impose the burden of proof on an initial applicant.

c. Judicial Review

Some commenters complained that section 7.35.3.25(E) wrongly limits judicial review. That section states that, "[e]xcept as otherwise provided by law, there shall be no right to judicial review of a decision by the administrative review committee." In essence, this states that the rule is not establishing a right to judicial review of such decisions, and that there is no right of review "except as otherwise provided by law". The Department is not required to establish a right of judicial review of such decisions by rule.

11. Records Retention, Fees, and Minor Consent

One commenter requested that the rule include specific record-retention periods, and that it establish a minimum patient age or consent architecture for minors. In consideration of this comment, the Department proposes to add to the rule a requirement that healing centers, practitioners, and facilitators retain treatment records for a minimum of five years, consistent with the retention period applicable to educational centers. With respect to a minimum patient age, the statute does not establish one, and the Department believes this is best left to the licensed provider to determine within their practice and within the patient-provider relationship.

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

Sincerely,

/s/ *Christopher D. Woodward 11-9-26*
Christopher D. Woodward
Deputy General Counsel