PUBLIC COMMENT ON NMAC 7.35.3

This public comment is submitted jointly by Healing Advocacy, Psychedelic Mental Health Access Alliance, and Rudick Law Group in response to draft rules. Our public comment focuses on features of the draft rules that are likely to unnecessarily limit patient access, complicate insurance coverage, drive up patient cost, and unnecessarily inflate departmental regulatory and administrative burden, raising program costs to the state. We are committed to the success of the state program, and are committed to being collaborative partners and resources throughout rulemaking and implementation.

I. Significant Program Design Concerns: Certifying Clinician, Patient Application, Supervision Structures

The draft rules contain significant design concerns that threaten to impact patient access and the long-term viability of the state program.

A. *Certifying Clinician Design Exceeds Statute and Misunderstands Safety in Psychedelic-Assisted Therapy*

We continue to warn against the proposed certifying clinician design. The proposed certifying clinician design misunderstands the safety requirements of this program and requires redress if New Mexico intends to build a safe and accessible program.

The design choice would require any patient who is seeking psilocybin care to be seen by a specially-permitted DOH prescribing clinician provider in an in-person encounter with limited exceptions for telehealth. As the Department has explained in public meetings, the design tracks the state's medical cannabis program, and the regulations read almost identically to those for "practitioners" in the medical cannabis program. The statute governing medical cannabis specifically required a prescribing clinician to assess a patient for the medical appropriateness of cannabis. No such requirement is present in the Medical Psilocybin Act, which carries the following two definitions:

> **"clinician"** means an **approved health care provider** licensed in New Mexico who holds a permit from the department to provide medical services to qualified patients
>
> **"qualified patient"** means a patient whose clinician has judged the patient to be a medically appropriate candidate for the use of medical psilocybin **based on being diagnosed with a qualifying condition**

Read together, these definitions create the legal parameters for patient entry in the Medical Psilocybin Program. All that is required under the statute is a qualifying condition, which can be confirmed by any licensed healthcare provider in New Mexico with authority to diagnose and treat these conditions. The certifying clinician design greatly exceeds this statutory framework.

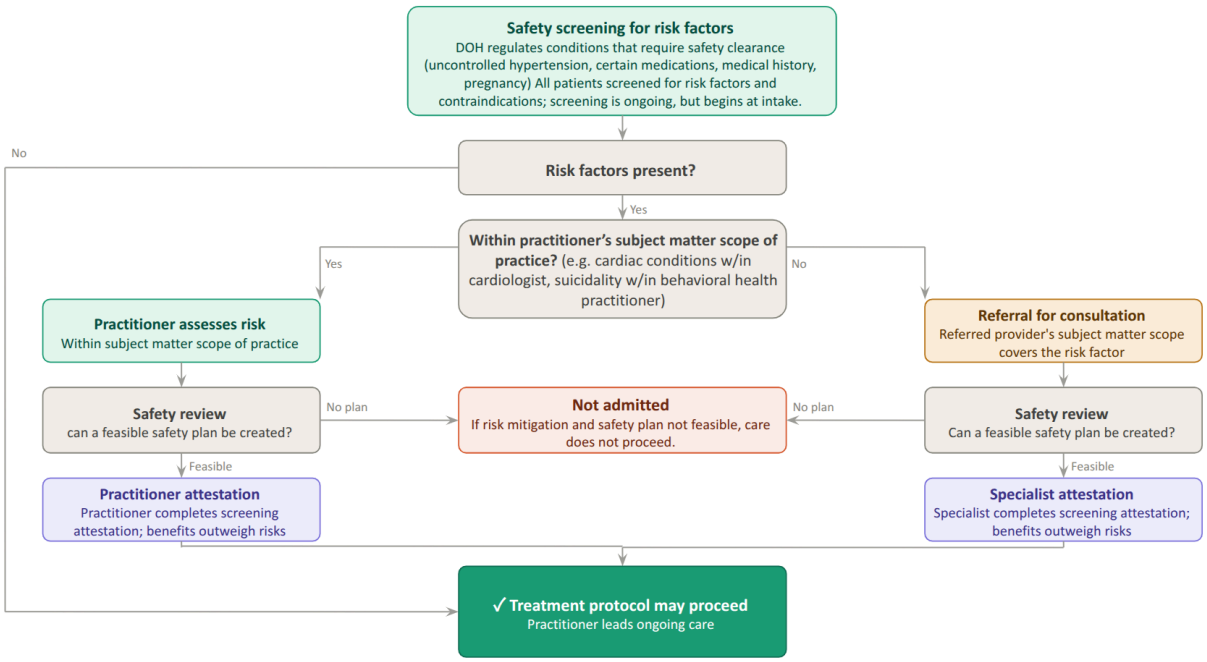
Health and safety screenings are important to building a safe program and should be regulated by the Department, but the certifying clinician design misunderstands how true medical concerns and safety risks present in a context of psilocybin-assisted therapy. By delegating safety and health screening to a prescribing provider gateway mechanism, the program assumes that risks will primarily be static (not changing over the course of treatment) and pharmacological, but this is far from true. The most significant risk factors in psilocybin-assisted therapy are psychological in nature and medical risks that require screening the day of administration (e.g. pregnancy, intoxication). These are missed in a safety system that assumes prescriptive authority upon entry equals medical safety.

In a safe psilocybin treatment model, safety screenings are ongoing, are conducted by the team most closely relating to the patient throughout their preparation, and are assessed by clinicians whose subject matter scope of practice aligns with the particular risk. Where that necessary expertise is not held by the primary care team, expert referrals and consultations are made to clinicians with appropriate expertise before treatment continues.

We recommend the Department remove the certifying clinician design. Many patients with qualifying conditions will not have contraindications, and rather than the blanket certifying-clinician model of Medical Cannabis, the Department should regulate around specific contraindications, medical histories, and medications that warrant clinical review (e.g. certain medication interactions, uncontrolled hypertension, history of psychosis, etc).

Where a risk factor is identified, the Department can require a clinician attestation that screening was conducted and that benefits outweigh risks. Such additionally required health screening should be conducted by a clinician whose subject matter scope of practice fits the patient's individual risk.The need for referral to conduct the risk factor follow up and assessment follows the practitioner's existing medical license: where a risk factor falls within the facilitator's subject matter scope of practice, the facilitator may proceed. Where it exceeds that scope, referral to a clinician whose license covers the relevant clinical area is required.

This model directs specialized review to patients who need it without imposing a universal requirement on program entry. The model would function as diagramed on the next page:



Additionally, the Department should consider requiring same-day pregnancy and drug testing. Poly-intoxication and unknown pregnancy status are commonly observed risks across many forms of psychedelic-assisted therapy, and the complications arising from both are preventable by a simple urinalysis.

In discussion, the Department has objected to this proposed revision on the grounds that it relies on patient attestation of health history rather than a medical exam. We share patient safety as our top priority. Our recommended protocol is based on the objective assessment of psilocybin's physiological risk profile, which is extremely low. The relevant medical risks are drug interactions — screenings for which already rely on patient attestation, regardless of who administers the screening – and hypertension, a condition for which any practitioner or facilitator can be trained to screen. Psilocybin's behavioral health contraindications (e.g. suicidality, personal or family histories of psychotic disorders or bipolar disorder) are conditions for which screening already relies on patient attestation. Consequently, appropriate and necessary health and safety screenings can be carried out without creating the barrier of the program's prescriber-gateway design.

If the Department remains unwilling to consider an alternative design, we want to further recommend strategic targeting of the limited provider base that will be able to fill this entry point role. In addition to targeting the Medical Doctors, Nurse Practitioners, Psychiatrists and other traditional prescribing providers, we recommend that DOH target the additional healthcare provider types who have been giving prescriptive authority in New Mexico: naturopathic doctors, acupuncturists, and chiropractors. These provider types have been specifically targeted to expand primary care access in New Mexico in address our longstanding provider shortage. These are also providers who have unique holistic health training, which is well-suited for the

kind of dynamic, health screenings that are most effective to keeping patients safe under psychedelic care.

B. Patient Application Inappropriate in Supervised-Use Program

The patient application process in the draft rules is unnecessary and should be stricken.

This seems to be another place where the Department has chosen to adopt a provision from the medical cannabis program without analysis of whether it is appropriate in the unique context of psilocybin. The “patient identification card” structure of the state’s medical cannabis program arises from a framework in which authorized patients will possess for legal medical use what would otherwise (at the time the Act was passed) be an illegal substance. To handle this, the Lynn and Erin Compassionate Use Act directly created a patient application process and endowed the Department of Health with duty to develop a process for reviewing and approving or denying those applications.

The medical psilocybin program operates quite differently. Because it relies on a model of supervised administration in approved locations only, no patient will legally possess psilocybin outside of that supervised episode. Therefore, there is no scenario in which a psilocybin therapy patient will need to prove their authorization to possess psilocybin, and thus no need for patient identification cards or applications.

The decision to replicate this model will, inappropriately and without any legal or policy justification, introduce tremendous administrative burden for the Department, add additional patient care wait times, introduce additional potential for patient data to be accessed without consent or unlawfully exfiltrated, and further stigmatize psychedelic-assisted therapy patients. The application process should be stricken.

C. Liability Concerns Regarding Supervision Structure Between Practitioners and Facilitators

At various points, the draft regulations create supervisory relationships between permit-holders (for example, the supervision of facilitators by practitioners). Supervisory roles carry liability for the conduct of those supervised, and in a medically-integrated model this takes on particular significance. Where a facilitator is not a medical professional and is not otherwise subject to the Medical Malpractice Act, placing that facilitator under a practitioner's supervision may inadvertently bring the facilitator's conduct within the supervising practitioner’s malpractice exposure, while leaving the facilitator outside the coverage framework that would ordinarily accompany that exposure. The facilitator could effectively be subjected to the Act’s liability consequences without access to the malpractice coverage the Act provides. This asymmetry could undermine the program’s ability to build the integrated clinical workforce it requires.

D. Long Lead Liability Problems with these Design Features

The issues identified above carry long lead liability problems, problems that may take years to surface but that will ultimately bear on the program's long-term viability. The most significant of these involves third-party payers.

The certifying clinician role as designed creates substantial risk of claim denials and clawbacks. Because the role exists solely to facilitate entry into a psilocybin therapy program, the clinical encounter it creates lacks a clearly defensible basis for independent medical necessity, which is precisely the standard insurers apply when evaluating coverage. We recognize that HCA offered reassurances on this point during a summer Advisory Board meeting, and we appreciate that engagement. However, regulatory structures cannot be built around current agency leadership, interpretations, or directives that will inevitably change. A clinical encounter that exists to authorize participation in a Schedule I substance program, rather than to address an independent medical need, will invite scrutiny over time, and coverage counsel for both public and commercial payers will look to the regulations themselves for grounds to deny claims or pursue clawbacks. Commercial insurers in particular operate under different incentive structures than HCA and are likely to apply considerably more scrutiny.

This is a further reason the Department should adopt the alternative patient flow proposed above. For patients who already have a diagnosis and an established care team, the sole function of the certifying clinician encounter is program entry. Creating a mechanism for these individuals to proceed directly to the components of care with clear, independent medical necessity (safety screening, preparation therapy, and related service) protects both patients and the program's long-term financial viability.

The supervisory relationships the regulations create between clinically licensed practitioners and non-clinically licensed facilitators are likely to generate significant third-party payor problems beyond the malpractice exposure already described. The core issue is that services rendered by unlicensed or non-clinically credentialed individuals are generally not reimbursable by health insurance. With narrow exceptions (for example, chaplain services in hospice care under Medicare, certified peer support workers under New Mexico Medicaid) insurers do not reimburse services delivered by people who fall outside recognized billing taxonomies. Where a regulation creates a supervisory or assistive relationship between a clinician (practitioner) and a non-clinician (facilitator), a payor reviewing a claim may characterize services billed under the practitioner's credentials as having been delivered, in whole or in part, by someone not authorized to bill, exposing the practitioner to claim denial, clawbacks, or other more serious consequences such as fraud.

The solution is not to pretend that practitioners and facilitators do not work together. They do, and the regulations should reflect that clinical reality. The problem is regulatory language that places one within the formal supervisory authority of the other in ways that blur billing boundaries. We recommend the Department treat the roles of practitioners and facilitators as legally and professionally independent within the regulatory framework, while separately articulating the ways in which they may coordinate care. A coordination or collaboration model (in which practitioners and facilitators communicate about patient care without a formal supervisory relationship) preserves the clinical integration the program depends on without

creating the payor exposure that a supervisory structure produces. Clear role delineation in the regulations would also give practitioners a defensible basis for billing only for the services they personally render, protecting both providers and the program from downstream clawback risk.

II. Other Issues Impeding Access

A. *Landlord Attestation for Other Approved Locations Should Not Apply to Patients Seeking Care in Their Home or in Residential Living*

We are grateful that the Department has developed an approval process for "other approved locations" for treatment that happens outside of a licensed Healing Center. One requirement on that approval process should be clarified. An application for care occurring in an "other approved location" currently requires:

> "Proof of ownership by the qualified patient or attending practitioner or facilitator of any property on which medical psilocybin administration sessions will be conducted, or a signed, written statement from the owner of such property acknowledging that the owner understands that persons will be participating in the medical psilocybin program on the premises, and what those persons are authorized to do within the terms of their certification."

As written, this requirement applies to any property where an administration session occurs, including a patient's own home. For end-of-life patients and other patients who receive in-home care and who rent rather than own their residence, the provision seems to require them to obtain a signed statement from their landlord acknowledging their participation in the Medical Psilocybin Program and describing what they are authorized to do under their certification, before they can receive care in their own home.

From Advisory Board meeting discussions of this provision, the Department has acknowledged that this is another feature borrowed from the medical cannabis program. Cannabis is typically smoked or vaporized, and a landlord has a real, practical interest in knowing whether that will occur on their property, given the potential effects on odor, ventilation, and property value. Medical psilocybin administration is a different clinical model and will happen only in a supervised session administered by a licensed facilitator, involving no smoking or lingering property effects of any kind. The property-owner interest that justifies the cannabis provision simply is not at all present in Medical Psilocybin.

The Department has suggested that – even though psilocybin is not a smoked drug – ongoing federal illegality alone justifies the required landlord's permission. However, New Mexico already made the decision to depart from federal law, a calculated choice to put our state values above misguided federal judgment in recognition of the profound potential of psilocybin to facilitate healing. Granting landlords authority to impede the healing of vulnerable and disabled patients

is contrary to these values. For these reasons, Commenters endorse the revision recommended to the Department by End of Life Options New Mexico, copied here:

> "This provision shall not apply to end-of-life patients or others seeking in-home care, or to long-term care facility residents."

Commenters note that failure to make these revisions is likely to expose the Department to liability under state law protections against discrimination. Similar litigation in Oregon on behalf of home-bound patients has already cost the Oregon Health Authority hundreds of thousands of dollars and is still ongoing.

III. Additional Safety Gaps

A. Minimum Hours Should be Assigned to Certain Didactic Topics

Commenters appreciate that the draft training requirements have seen significant improvement through the advisory board process and commend the Department for collaborating with subject matter experts to bring regulations closer to the educational and safety standards of the psychedelic field. However, two content areas also appear to be missing entirely: suicidality and challenging experiences. Given that treatment-resistant depression and PTSD are among the qualifying indications, these topics are key to ensure safety in the program.

We also recommend that certain content areas be assigned minimum hour requirements, to ensure that training programs deliver sufficient education on topics that are key to patient safety. We suggest the following minimum hours be assigned to the following topics:

- Suicidality screening and crisis response — 5 hours
- Challenging experiences, including de-escalation — 4 hours
- Pharmacology, drug interactions, and clinical research — 5 hours
- Trauma and trauma-informed care — 7 hours
- End-of-life care — 5 hours

Thank you for considering this feedback. We look forward to participating in the October 2, 2026 hearing and to offering any support we can to the Department in resolution of the above identified issues.