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POLICY SERIES

Urgency Without Compromise: Building Safe, Equitable Access to Psychedelic-Assisted Therapy

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Now is the time to address the growing behavioral health needs across our country by advancing public policies that transform how mental health and substance use disorder services are delivered—and by modernizing outdated funding systems that stand in the way of progress.

This paper is part of *Think Bigger Do Good*, a series launched in 2017 through the leadership and support of the Thomas Scattergood Behavioral Health Foundation and Peg's Foundation. While the topics have evolved over time, our mission remains constant: to shape a forward-thinking policy agenda that improves health outcomes for all.

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Urgency Without Compromise: Building Safe, Equitable Access to Psychedelic-Assisted Therapy

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Abstract

Psychedelic-assisted treatments are often framed as pharmacologic innovations, yet their clinical effects appear to depend substantially on context, relationship, training, and systems of care that are not easily standardized or scaled. At the same time, these treatments are being developed and accessed through heterogeneous pathways, including clinical trials, limited state-level programs, and unregulated settings, in the absence of mature clinical infrastructure. Although there is ongoing debate regarding the relative contributions of pharmacology, subjective experience, and psychotherapy, most current treatment models incorporate structured preparation, support during administration, and post-session integration. As access expands without consensus on optimal models of care, there is a risk that implementation will prioritize scalability over clinical integrity, potentially diminishing effectiveness, increasing harm, and distorting clinical judgment. This paper argues that sustained clinician leadership is necessary to guide the development of care models that preserve safety, support therapeutic processes, and maintain long-term clinical accountability. It outlines practical roles for clinicians, health systems, and philanthropy in shaping the infrastructure required to responsibly implement these treatments.

Note from the authors

This paper examines emerging clinical considerations and system-level responsibilities in the development of psychedelic-assisted therapy. It is not intended to establish formal standards of care or replace clinical judgment, which must be applied in the context of individual patient circumstances and evolving evidence.

Introduction

Psychedelic-assisted therapy has shown promising results in clinical research, particularly for posttraumatic stress disorder (PTSD), where randomized controlled trials have demonstrated clinically meaningful effects (Zaretsky et al. 2024; Mitchell et al. 2023), and for major depressive disorder (Ross et al. 2016; Raison et al. 2023; Davis et al. 2021), and alcohol use disorder (Bogenschutz et al. 2022), where smaller trials suggest potential benefit. Evidence for other indications remains preliminary (Johnson 2022; Mithoefer, Grob, and Brewerton 2016; Johnson and Griffiths 2017).

At present, psychedelic-assisted treatments are not approved for routine clinical use in the United States and are not broadly available within regulated systems of care. At the same time, access is expanding through clinical trials, limited state-level programs, and unregulated settings, creating a widening gap between demand and established clinical infrastructure. As a result, patients with complex conditions who have not sufficiently benefited from other approaches may increasingly seek care outside established health systems. Policymakers and practitioners therefore face a central challenge: how to respond to urgent, unmet needs while building the clinical, organizational, and workforce infrastructure required to deliver these interventions safely and consistently.

Access has expanded outside traditional clinical systems, including through state-level initiatives, unregulated use, and international treatment pathways, rather than through established models of care (Luoma et al. 2025; Rockhill et al. 2025; Neitzke-Spruill et al. 2025). These developments highlight the absence of a coordinated framework for safe, equitable delivery and underscore the need to define how such systems should be structured.

Establishing such a system involves more than introducing new medications into existing mental health frameworks. Psychedelic-assisted treatments do not fit a conventional prescribing model in which a medication is dispensed with limited clinical contact. Instead, they require extended clinician time, direct presence during administration, and structured follow-up. Available evidence suggests that clinical outcomes are shaped by this broader therapeutic context—one that current delivery systems are not designed to accommodate.

The development of this new architecture will require sustained clinical leadership. To this end, we outline defining features of psychedelic-assisted therapy; identify clinical, ethical, and systems-level risks that arise when clinicians are peripheral to emerging models of care; and examine how clinician engagement can support the development of safe, durable, and accountable systems.

What Is Psychedelic-Assisted Therapy?

Psychedelic-assisted therapy refers to a structured clinical intervention in which the administration of a psychoactive compound is embedded within a therapeutic framework that includes preparation, monitored dosing, and post-session integration. At present, there is no single, agreed-upon model of how these treatments exert their effects. Ongoing debates in the field center on the relative contributions of pharmacology, the subjective experience induced by the drug, and the role of psychotherapy. Some approaches emphasize the neurobiological effects of the compound, others focus on the experiential or psychological dimensions, and still others attempt to minimize the intensity or relevance of the altered state. Comparative evidence across these models remains limited.

Despite this lack of consensus, most contemporary clinical protocols incorporate at least some combination of preparatory sessions, psychological support, or psychotherapy during the dosing experience and post-session integration. The structure, intensity, and theoretical orientation of these components vary considerably across compounds, indications, and treatment settings. It is likely that different disorders—and different pharmacologic agents—will ultimately require distinct therapeutic approaches.

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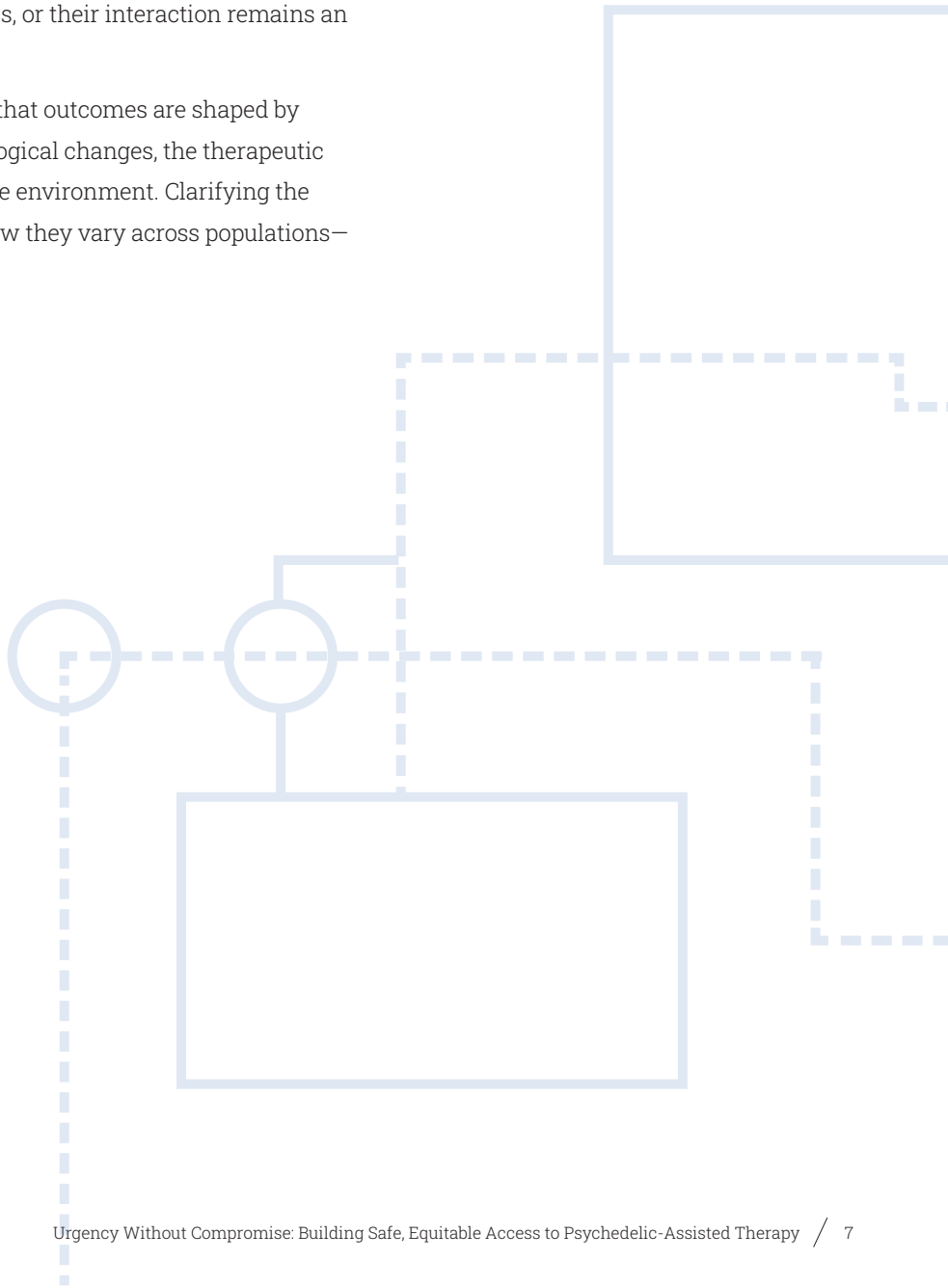
Clinical observations and trial designs to date suggest that the subjective experience is often associated with therapeutic outcomes, although the nature of that relationship remains incompletely understood. While it is possible that some benefits may be achieved with reduced or altered subjective effects, many current models treat the acute experience as therapeutically relevant rather than incidental.

In this context, we view one of the defining features of psychedelic-assisted therapy as the opportunity for patients to access and work with material that emerges during the altered state. Preparation and integration are therefore not simply supportive elements, but processes that help patients engage with, interpret, and incorporate these experiences into ongoing psychological and behavioral change. At the same time, the extent to which therapeutic effects depend on the subjective experience itself, the surrounding psychotherapeutic process, or their interaction remains an open empirical question.

Taken together, the available evidence suggests that outcomes are shaped by multiple interacting factors, including neurobiological changes, the therapeutic relationship, psychotherapy, and the broader care environment. Clarifying the relative contributions of these elements—and how they vary across populations—remains a central task for ongoing research.



Why Clinician Engagement Remains Limited

Despite growing interest in psychedelic-assisted treatment, our experience has shown that many clinicians remain cautious about direct participation. This hesitation likely does not reflect resistance to innovation, but a rational response to structural ambiguity in training, standards, accountability, and sustainability.

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Training and Competency

Training pathways often remain heterogeneous and inconsistently specified, although efforts to standardize elements are underway. Core competencies, supervision requirements, and thresholds for independent practice are often unclear, particularly in areas such as complex trauma, dissociation, and longitudinal integration. There is also limited consensus regarding how psychotherapy functions as a constitutive component of the intervention rather than an adjunct to pharmacology.

Evidence and Implementation Gaps

Existing clinical trials demonstrate efficacy under tightly controlled conditions (Luoma et al. 2020) but provide limited guidance for real-world implementation. Important questions remain regarding effectiveness relative to current standards of care, durability of benefit, and risk stratification across heterogeneous populations. These gaps hinder the development of quality benchmarks, reimbursement models, and accountability frameworks.

Clinical Integration and Responsibility

It remains unclear how psychedelic-assisted treatment should be embedded within existing systems of care. Key issues include longitudinal responsibility, care transitions, management of delayed destabilization, and coordination with other services. In the absence of clear protocols and institutional support, clinicians may be hesitant to assume responsibility.

Regulatory Barriers

Evolving state policies, scope-of-practice rules, enforcement environments, and uncertainties in approval pathways contribute to ambiguity regarding professional risk. In the absence of stable regulatory frameworks, clinicians and service organizations face unclear liability exposure.

Economic Infrastructure

Sustainable reimbursement pathways remain underdeveloped. In the absence of predictable funding models, participation frequently depends on uncompensated labor or cross-subsidization, limiting both scalability and equity. These conditions place clinicians in a position of high responsibility paired with diffuse standards, uncertain accountability, and fragile institutional support. For risk-aware practitioners, caution is not obstruction—it is professional prudence.

Why Clinician Involvement Is Necessary in Building Psychedelic-Assisted Therapy Systems

Excluding clinicians from the design and governance of psychedelic-assisted therapy systems carries significant risks. Clinical leadership is essential not only for patient safety, but for preserving the integrity of the therapeutic model as infrastructure develops. The following examples illustrate how the absence of clinician involvement may shape emerging systems in ways that compromise safety and effectiveness.

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Limited Safety Frameworks

Safety risks may be narrowly operationalized in the absence of clinician leadership. Frameworks may prioritize pharmacological risk management while underweighting the relational and longitudinal dimensions of care, including preparation, psychotherapy, integration, supervision, and ongoing responsibility. Systems may also fail to anticipate trauma activation, dissociation, suicidality, or delayed destabilization following treatment. Clinicians are uniquely positioned to ensure that safety encompasses both acute physiological risk and longer-term psychological stability.

Risks of Over-Standardization

The intervention may be redefined by what is easiest to standardize. Regulatory and commercial frameworks tend to prioritize elements that are measurable and scalable—such as dosing protocols, session counts, short-term symptom endpoints—while underrepresenting dimensions that are more difficult to codify, including therapeutic process, clinician judgment, longitudinal integration, and relational context. Over time, this may distort how competence, safety, and effectiveness are operationalized across training, reimbursement, and oversight structures. Meaningful clinician involvement is necessary to ensure that standards encode, rather than erase, clinical judgment.

Non-clinical Incentives in Care

Non-clinical incentives can shape emerging models of care. In the absence of sustained clinician engagement, system design may prioritize commercial convenience, regulatory expediency, or molecule-centric approval processes over patient-centered care architecture. When clinical leadership is peripheral, decisions about delivery models, workforce roles, and quality benchmarks risk drifting away from the realities of complex psychiatric care.

Path Dependence in System Design

Early design choices are durable. Standards of practice, reimbursement mechanisms, training pipelines, and governance structures tend to become embedded in regulatory and institutional systems. If clinical judgment is not integrated at the outset, recalibrating these systems after scale has occurred will likely be costly, politically difficult, and potentially destabilizing to patient care.

How to Involve Clinicians

Meaningful clinical engagement involves more than advisory representation; it requires structured roles in defining, operationalizing, and governing psychedelic-assisted treatment systems. The following domains outline where such engagement is necessary.

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1 **Specify the intervention and its competencies**

Psychedelic-assisted treatment must be defined beyond dosing protocols or session counts. Clinical leadership is essential in articulating the full therapeutic architecture, including preparation, monitored dosing, psychotherapy, integration, supervision, and longitudinal responsibility. Clinicians should define therapeutic roles, scope of practice, core competencies, thresholds for independent practice, and supervision standards. All clinicians involved in this work require grounding in trauma-informed care, risk assessment, support during altered states, and principles of longitudinal integration. Because medicine, nursing, psychology, and social work entail distinct scopes of practice, supervisory responsibilities, and clinical liabilities, some components will need to be discipline-specific. Accordingly, training programs should be developed by subject-matter experts who can balance shared standards with discipline-specific obligations, rather than relying on generic credentialing frameworks.

2/ Embed clinical judgment into standards, data, and accountability

What systems measure and reimburse ultimately shapes clinical behavior. Clinicians should therefore be directly involved in determining which outcomes meaningfully reflect stability, functional improvement, and risk reduction over time. Implementation data can help inform quality benchmarks, safety monitoring, and reimbursement models, reducing reliance on short-term trial endpoints. Comparative assessment against existing standards of care may support responsible quality improvement without implying premature claims of superiority.

3/ Integrate into existing clinical systems

Integration into existing clinical systems is critical, particularly for higher-acuity populations. Embedding psychedelic services within established care structures can clarify patient selection, continuity of responsibility, escalation pathways, and long-term monitoring, while reducing fragmentation across settings. Health system-based demonstration sites are especially important for developing and refining workflows, supervision structures, and support practices prior to implementation. Integration also enables coordinated care for patients with co-occurring medical, psychiatric, and social complexity.

4/ Stabilize professional risk and sustainability

Scope-of-practice standards, supervision norms, and liability expectations require direct clinician involvement in regulatory and policy processes. Clinical representation within industry and health-sector governance structures may help mitigate conflicting commercial and therapeutic incentives. Early infrastructure development may also require targeted philanthropic investment to support demonstration sites and workforce development.

Conclusion

Psychedelic-assisted therapies offer a potential approach for people whose needs are not adequately addressed by current mental health systems. This paper focused on how clinician involvement in designing treatment environments may determine whether that potential is realized.

The therapeutic potential of psychedelic-assisted therapy depends fundamentally on the context in which it is delivered. These interventions require systems that support coordinated preparation, monitored dosing, integration, longitudinal responsibility, and continuity of care—features that cannot be reduced to pharmacology or readily incorporated into fragmented care environments.

Emerging delivery models do not consistently reflect this treatment framework. Many originate within pharmaceutical development frameworks designed to achieve regulatory approval and market viability. While these frameworks may appropriately prioritize standardization, reproducibility, and short-term endpoints, they tend to underemphasize the nonpharmacological components that are central to therapeutic effectiveness. These risks are likely to persist. Early infrastructure decisions will shape training standards, reimbursement structures, accountability frameworks, and patient safety norms for years to come.

Clinician leadership should be foundational, not ancillary to, the development of psychedelic-assisted therapy. The design of treatment environments—rather than the properties of the drug alone—will determine how these interventions function in practice.

As access continues to expand outside regulated systems of care, professional organizations and clinical guilds face a consequential choice: to define standards of care, training, accountability, and integration, or to allow these systems to be shaped by market forces, regulatory expediency, and informal networks. The central question is whether mental health professions will determine the operating logic of psychedelic-assisted therapy systems or inherit it.

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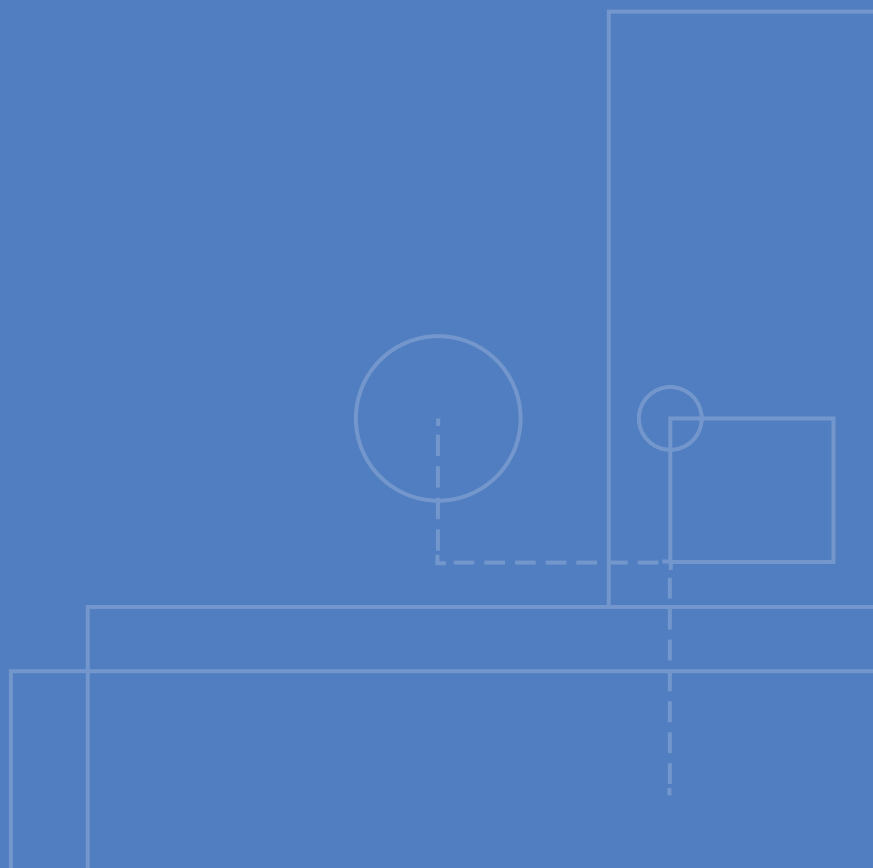

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