August 13, 2026

Thomas J. Engels, Administrator
Health Resources and Services Administration
Department of Health and Human Services
5600 Fishers Lane, Room 13N194
Rockville, MD 20857
Submitted via www.regulations.gov

Re: **Request for Information, Training and Care Delivery Models for Safe Administration of Potential FDA-Approved Psychedelic Therapies in Ambulatory Clinical Settings**

Dear Mr. Engels:

On behalf of BrainFutures, Mental Health America, the National Council for Mental Wellbeing, and Meadows Mental Health Policy Institute, thank you for the opportunity to respond to the Request for Information (RFI) regarding Training and Care Delivery Models for Safe Administration of Potential FDA-Approved Psychedelic Therapies in Ambulatory Clinical Settings.

As SAMHSA's latest data illustrates, America is still in a mental health and substance use disorder crisis. In 2025, approximately one in five adults (54.6 million) had experienced mental illness in the past year; 6.9% (18.2 million) had a serious mental illness; and 15.3% of people 12 and older (44.6 million) had a substance use disorder.[1] Patients need innovative new treatments, and a number of psychedelics have shown very promising results in addressing conditions including major depression, treatment-resistant depression, post-traumatic stress disorder, and substance use disorders.

FDA approval of a psychedelic medication could occur within the year. However, FDA approval alone will not bring innovative psychedelic treatment into reach for the people who most need it. Collaborative preparation will be required to ensure that patients gain access to approved psychedelics in a safe, ethical, and affordable way. Meanwhile, psychedelics introduce several service delivery questions that require added attention and planning.

We therefore greatly appreciate that the Health Resources and Services Administration (HRSA) is taking deliberate steps to plan for supporting access to FDA-approved psychedelics. HRSA's leadership in health workforce development underscores the importance of the agency's attention to the training and other supports that will be needed for psychedelic treatment. In addition, HRSA plays a crucial role in reaching underserved communities through its administration of programs including Federally-Qualified Health Centers, Rural Health Centers, and other safety-net clinic programs. We look forward to working with HRSA and other partners in this process.

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[1] Substance Use and Mental Health Services Administration, "2025 National Survey on Drug Use and Health (NSDUH) Releases" (July 27, 2026). Available at www.samhsa.gov/data/data-we-collect/nsduh-national-survey-drug-use-and-health/national-releases/2025

About the Organizations

BrainFutures is a national non-profit that works to advance the practical application of promising brain health interventions and expand access to treatments and technologies. BrainFutures was launched in 2015 by the nation's second oldest mental health advocacy organization, the Mental Health Association of Maryland (MHAMD). For more than 100 years, MHAMD has addressed the mental health needs of Marylanders of all ages through programs that educate the public, advance public policy, and monitor the quality of mental healthcare services. Building on this success and bolstered by a cross-disciplinary advisory board of leading experts, BrainFutures brings together diverse stakeholders and policymakers to support and accelerate the national adoption of effective practices in brain health. BrainFutures' recent work includes a series of reports on psychedelics that have been widely utilized by policymakers, advocates, and business leaders in the field of medical psychedelics.

Mental Health America (MHA) is the nation's leading non-profit dedicated to promoting the mental health and well-being of all people living in the U.S. With a network of 130 affiliates in 38 states, MHA works at both the national and local levels to advance our mission through public education, research, advocacy and public policy, and direct service. Founded in 1909 by Clifford Beers, who suffered abuse in psychiatric facilities and advocated for reforms, MHA continues his legacy by educating policymakers on the impact of public policies on people with mental health conditions and substance use disorders.

The National Council for Mental Wellbeing (National Council), founded in 1969, is a membership organization that drives policy and social change on behalf of over 3,200 mental health and substance use treatment organizations and the more than 15 million people they serve. The National Council advocates for policies to ensure access to high-quality services, builds the capacity of mental health and substance use treatment organizations, and promotes greater understanding of mental wellbeing as a core component of comprehensive health and health care. Through the Mental Health First Aid (MHFA) program, the National Council has trained over 5 million people to identify, understand and respond to mental health and substance use challenges.

The Meadows Mental Health Policy Institute is an independent and nonpartisan organization that works at the intersection of policy and programs to create fair and effective systemic changes so all people in Texas, the nation, and the world can obtain the health care they need.

Our organizations have a successful track record of collaboration to advance the integration of psychedelic therapy into the behavioral health system. Staff from the National Council and Meadows Mental Health Policy Institute serve on an advisory committee overseeing the development of a national summit, Frontiers of Mental Health and Recovery, a convening that BrainFutures is developing to advance psychedelic therapy. Staff from Mental Health America serve on a national working group convened by BrainFutures to develop interdisciplinary core competencies for psychedelic therapy (described further below). Together, our organizations bring complementary expertise and experience to inform the safe, effective and sustainable integration of psychedelic therapy into healthcare and behavioral health systems.

General Comments

We are excited that HRSA is supporting the development of proper infrastructure for safe and effective delivery of new innovative treatments, especially given the need for additional effective treatment options for people with mental health and substance use disorders.

While the recommendations we make here apply generally to psychedelic therapy, the category of "psychedelics" reflects a class of psychoactive substance with significant variation in compounds, delivery mode, and effects. Training and protocols may vary by substance.

Workforce and delivery needs may also vary depending on the patient population. Phase 3 clinical trials are underway for a range of indications including treatment-resistant depression, major depressive disorder, generalized anxiety disorder, post-traumatic stress disorder, suicidal depression, and severe alcohol use disorder.[2] Phase 1 and 2 trials are focusing on these and other behavioral health indications, including postpartum depression and binge eating disorder, as well as non-behavioral health conditions including fibromyalgia and migraines.[3] Provider trainings and treatment protocols must be adaptable to meet the needs of patients with different diagnoses.

In addition to varied health needs, patients will bring different treatment histories to psychedelic treatment. For example, the needs of a patient who has had consistent access to mental health services will contrast with someone who has been experiencing untreated illness. Approaches to psychedelic therapy must be flexible enough to meet individual patients' needs. We also recommend specific considerations based on stage of human development, as patients of different ages may need different supports.

We offer below responses to questions from several sections of the RFI. Our comments draw from the Professional Practice Guidelines for Psychedelic-Assisted Therapy, published in 2023 by BrainFutures and the American Psychedelic Practitioners Association,[4] and other sources as indicated. Developed by expert researchers and clinicians, the Professional Practice Guidelines aim to support mental health providers in delivering psychedelic treatment that is integrated with therapy during the same treatment session.[5] These guidelines will be updated in 2027 to reflect the growing body of clinical and implementation evidence for psychedelic therapy.

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[2] Psychedelic Alpha, Psychedelic Drug Development Tracker (Accessed July 30, 2026). Available at https://psychedelicalpha.com/resources/psychedelic-drug-development-tracker/

[3] *Id.*

[4] American Psychedelic Practitioners Association and BrainFutures, "Professional Practice Guidelines for Psychedelic-Assisted Therapy" (2023). Available at https://www.brainfutures.org/wp-content/uploads/2024/06/Professional-Practice-Guidelines-for-Psychedelic-Assisted-Therapy.pdf

[5] *Id.*

RFI Section 1: Workforce Training

Pre-administration patient eligibility, screening and counseling:

- **What training should be required of providers counseling, screening, and identifying patients eligible for psychedelic therapy?**
- **What competencies do providers need to achieve to serve patients in this phase of care?**

An interdisciplinary workforce of trained providers will be essential to meet the anticipated demand for psychedelic treatments. As detailed in the Professional Practice Guidelines, that training should be appropriate to the scope of practice for varying types of providers (Guideline 2), and providers should engage in ongoing education and training (Guideline 3).[6]

Unfortunately, most universities and clinical training sites lack the faculty expertise, curriculum infrastructure, and funding required to deliver comprehensive education in these modalities. For example, a 2024 survey of academic institutions conducted by BrainFutures and NORC found that the majority had insufficient faculty and funding for psychedelic treatment training.[7]

To address this gap, HRSA should support an interdisciplinary, competency-based training strategy. Training for psychedelic therapy care teams should be sufficient to ensure safety and efficacy, but not so burdensome that it creates barriers to patient access. Thus, community-based organizations and other non-academic organizations with expertise in patient needs should be able to partner to offer workforce training.

Some specific competencies for the pre-administration stage are detailed in the Professional Practice Guidelines. These include:

- Obtaining and documenting informed consent before commencing treatment and approaching consent as an ongoing process to be addressed at multiple points over the course of therapy. Informed consent should also address the potential applications of touch (Guidelines 4 and 5).
- Ensuring that patients have been comprehensively screened in accordance with existing evidence, guidelines, and clinical judgment (Guideline 6).
- Building rapport and trust with patients during the preparatory period (Guideline 7).
- Preparing patients for a medication administration session by inviting them to share their personal histories, explaining medication administration session logistics, reviewing the range of possible experiences during the medication administration session, discussing potential therapeutic approaches that may be used, providing guidance for navigating challenging experiences that could arise, and answering patient questions (Guideline 8).[8]

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[6] "Professional Practice Guidelines for Psychedelic-Assisted Therapy," *supra.*
[7] Knepler E, Smith R, Bautista M, et al. Survey on Psychedelic Therapy in Academia. December 2024. https://www.brainfutures.org/wp-content/uploads/2024/12/Survey-on-Psychedelic-Therapy-Curricula-in-Academia_Report.pdf
[8] "Professional Practice Guidelines for Psychedelic-Assisted Therapy," *supra.*

In addition, BrainFutures is currently leading a rigorous process to identify interdisciplinary core competencies for psychedelic therapy. The goals are to support safe and accessible delivery of FDA-approved psychedelic treatment and to inform the development of effective training and educational opportunities. The process is based on an evaluation of peer-reviewed literature combined with analysis of existing reports, curricula and training materials from professional organizations, psychedelic therapy training organizations, academic institutions, government agencies, and drug developers. An interdisciplinary expert workgroup has convened to discuss, draft, and vote on adoption of final competencies.

Current workgroup members include staff from national provider and consumer advocacy organizations including the American Psychiatric Association and Mental Health America, academic leaders from Johns Hopkins University and the University of California, clinical leaders from Sana Health and Mindful Health Solutions, a federal liaison from HHS; and a consumer representative who participated in a clinical trial.

We anticipate that the competencies will extend across 12 domains:

1. Informed Consent
2. Setting Management
3. Psychological Support and Psychotherapy
4. Ethics & Boundaries
5. Cultural Humility
6. Compliance & Risk Management
7. Psychedelic Pharmacology & Drug Interactions
8. Screening & Patient Assessment
9. Medical Monitoring & Crisis Intervention
10. Care Coordination
11. Outcomes Measurement
12. Safety and Basic Knowledge

Because the competencies are intended to apply across disciplines, the specific competencies needed will vary by provider type. For example, ethics will be important for all providers, while screening and assessment competencies may be more relevant for clinically trained providers. Employers, training programs, and others will be able to apply the competencies as appropriate for their workforce.

We anticipate completion of the competency development process by the end of 2026 or early 2027. These interdisciplinary core competencies will address many of the questions asked in this RFI. Accordingly, we will share the final product with HRSA at that time.

- **Should providers be required to have a professional degree (social work, psychologist, other)?**
- **Should providers be required to have a medical degree (physician, nurse practitioner, physician assistant, nurse, other), or not (peers or other trained non-professionals)?**

As outlined in the Professional Practice Guidelines, members of a psychedelic care team can have different degrees and professional backgrounds, depending on their role on the team.[9]

[9] "Professional Practice Guidelines for Psychedelic-Assisted Therapy," *supra.*

In addition, nonclinical peer support professionals and other unlicensed support staff can play important roles as part of a team that includes licensed health professionals. For example, with supervision, trained peers can monitor medication sessions and support patients during pre-administration and post-administration follow-up. There is a strong evidence base supporting the efficacy of peer support professionals in mental and behavioral health, as outlined in reports issued by Mental Health America and others.[10]

Integration of peer support and other unlicensed staff within psychedelic-supported treatment will be crucial for ensuring access, especially given the existing shortage of behavioral health professionals across the country. As of June 2026, HRSA's workforce data indicates that over 157 million individuals live in areas designated as Mental Health Professional Shortage Areas.[11] Supervised and trained peer support professionals and similar workers can help scale access to psychedelic treatment without further straining the mental health workforce.

Existing evidence-based resources support the integration and supervision of peers in behavioral health services.[12] The National Council for Mental Wellbeing, for example, advances peer support through specialized training, white papers,[13] and resources like Whole Action Management[14] to help individuals with lived experience integrate into behavioral health teams. These and other resources can be leveraged to facilitate the effective integration of peer support professionals and other unlicensed providers into psychedelic therapy care teams.

Additionally, several federal agencies offer guidance and support on integrating peer support services in various care settings. HRSA funds technical assistance for training and certification of peer specialists through its Behavioral Health Workforce Education and Training paraprofessionals program. The Substance Abuse and Mental Health Services Administration has funded five technical assistance centers to offer peer support technical assistance and placed its first peer specialist in leadership at the Office of Recovery to help treatment providers support access to recovery-based peer services. The Centers for Medicare and Medicaid Services has

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[10] See, e.g., Mental Health America, "Evidence for Peer Support" (2019), available at https://mhanational.org/wp-content/uploads/2025/02/Evidence-Peer-Support-May-2019.pdf; SAMHSA, "Value of Peers" (2017), available at https://www.samhsa.gov/sites/default/files/programs_campaigns/brss_tacs/value-of-peers-2017.pdf; Gaiser et al, "A Systematic Review of the Roles and Contributions of Peer Providers in the Behavioral Health Workforce" *American Journal of Preventive Medicine* (2021). https://www.healthworkforceta.org/wp-content/uploads/2023/07/BHWRC_Peers-in-the-Behavioral-Health-Workforce.pdf

[11] Designated Health Professional Shortage Areas Statistics. Health Resources & Services Administration. June 2026. Available at https://data.hrsa.gov/default/generatehpsaquarterlyreport

[12] See, e.g., SAMHSA, "Supervision of Peer Workers." Available at https://www.samhsa.gov/sites/default/files/programs_campaigns/brss_tacs/brss-209_supervision_of_peer_workers_overview_cp6.pdf

[13] See, e.g.,The National Council for Mental Wellbeing, "Advancing Person-Centered Care: Peer Support in Schizophrenia Care in Certified Community Behavioral Health Clinics" (2026). Available at https://www.thenationalcouncil.org/resources/advancing-person-centered-care/;

[14] The National Council for Mental Wellbeing, "Whole Health Action Management." Available at https://www.thenationalcouncil.org/service/whole-health-action-management/

published guidance to states[15] and providers[16,17] to increase the availability of peer support services in various clinical and non-clinical settings. The complementary and interagency work of HRSA, CMS, and SAMHSA should be leveraged to ensure behavioral settings appropriately integrate peer services into psychedelic therapy.

It is important to ensure that peer support professionals, including those with a history of justice system involvement, are welcomed and trusted as experts in clinical settings without bias or exclusion. Evidence shows that justice-involved peer support workers (and community health workers) increase patient engagement.[18] However, certain state codes prohibit certification of peer specialists for work in clinical settings when a history of substance use criminal offenses is present.[19] Individuals with mental health and substance use conditions are often criminalized prior to their recovery, yet this very experience makes them well-qualified to help individuals build trust in institutions including medical or integrated behavioral health settings delivering psychedelic treatment. We support efforts to develop policies that permit their inclusion on psychedelic care teams.

- **Is telehealth an appropriate means of screening and identifying patients for these therapies, and counseling patients on what to expect during psychedelic administration?**

Telehealth has become an established and important modality for behavioral health care, supported by a range of resources and practice guidelines.[20] Our organizations have worked to advance access through telemental health in numerous ways. For example, the Meadows Mental Health Policy Institute developed a guide to telehealth during the COVID pandemic, noting the

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[15] Centers for Medicare and Medicaid Services and SAMHSA. Frequently Asked Questions on Medicaid and CHIP Coverage of Peer Support Services (June 2024). Available at: https://www.medicaid.gov/federal-policy-guidance/downloads/faq06052024.pdf

[16] CMS Medicare Learning Network. Medicare and Mental Health Coverage. (July 2024) Available at: https://www.cms.gov/files/document/mln1986542-medicare-mental-health-coverage.pdf

[17] CMS Medicare Learning Network. Chronic Care Management Services. (May 2024) Available at: https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/chroniccaremanagement.pdf

[18] Treitler P, DiGioia-Laird V, Long B. Peer support services for individuals with health-related needs reentering the community after incarceration: a scoping review of program elements and outcomes. Health Justice. 2025 Aug 16;13(1):51. doi: 10.1186/s40352-025-00358-0. PMID: 40817968; PMCID: PMC12357432. https://pmc.ncbi.nlm.nih.gov/articles/PMC12357432/

[19] Nichols, M., Kues, D., Saubers, T., Comparative Analysis of State Requirements for Peer Support Specialist Training and Certification in the United States. Peer Recovery Center of Excellence (PRCoE).

[20] See, e.g., SAMHSA, "Evidence-Based Resource Guide Series: Telehealth for the Treatment of Serious Mental Illness and Substance Use Disorders" (2021), Available at https://library.samhsa.gov/sites/default/files/pep21-06-02-001.pdf; American Psychiatric Association, "Best Practices in Videoconferencing-Based Telemental Health" (April 2018). Available at https://www.psychiatry.org/File%20Library/Psychiatrists/Practice/Telepsychiatry/APA-ATA-Best-Practices-in-Videoconferencing-Based-Telemental-Health.pdf; American Psychological Association, "APA Guidelines for the Practice of Telepsychology" (2024). Available at www.apa.org/about/policy/telepsychology-revisions

importance of telehealth access even outside the pandemic context for underserved and rural communities.[21] The National Council for Mental Wellbeing has developed a video series to support effective, client-centered telehealth in behavioral health settings.[22] And, Mental Health America has been a leading advocate for extended telemental health flexibilities during the COVID pandemic and beyond. It is important to require that support is available to patients between telemental health appointments, should questions, concerns, or distress arise prior to or following an appointment.

In the context of psychedelic therapy, telehealth will likely serve a similarly important role, and we support its application. The forthcoming competency document will address the appropriate use of telehealth across stages of the process.

- **How do multiple providers (e.g., primary care and behavioral health providers) communicate plans for psychedelic therapies and/or collaborate to provide psychedelic therapies?**

The Professional Practice Guidelines recommend that providers of psychedelic therapy coordinate and communicate with other relevant providers, including primary care providers, relevant specialists, and other behavioral health providers (Guideline 12).[23] This coordination improves patient outcomes through better-informed care. For example, coordination with mental health providers can give the psychedelic therapy provider insight into patients' history and facilitate a smooth return to the usual source of care after psychedelic therapy is complete. Coordination with primary care providers and, if applicable, specialists will allow psychedelic therapy providers to identify medical risks or concerns and can reduce burden if existing physical exams and lab results are available. Where feasible, the use of electronic medical records that are available across providers can help facilitate coordination. While care coordination is a fundamental priority across behavioral health and healthcare, designing care coordination approaches requires careful attention to patient preferences and administrative burden.

It is important to note that the broader medical field, including those not administering psychedelic treatment, will need to develop an understanding of these medications in order to coordinate, make referrals, and answer preliminary questions from patients. We note that the Psychedelic Education Partnership is working toward this goal with programs for the emerging healthcare workforce (University Psychedelic Education Program, or U-PEP) and the existing clinical workforce (Clinician Psychedelic Education Program, or C-PEP).[24]

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[21] Meadows Mental Health Policy Institute, "Tele-Behavioral Health Primer: Current Knowledge and Best Practices" (2021). Available at https://mmhpi.org/wp-content/uploads/2022/12/Tele-Behavioral-Health-Primer_Current-Knowledge-and-Best-Practices.pdf

[22] The National Council for Mental Wellbeing, "CCBHC Telehealth Essentials: Practical Strategies for Connected Care" (2026). Available at https://www.thenationalcouncil.org/resources/ccbhc-telehealth-essentials-practical-strategies-for-connected-care/

[23] "Professional Practice Guidelines for Psychedelic-Assisted Therapy," *supra.*

[24] See Psychedelic Education Partnership, psychedeliceducationpartnership.org

In-clinic day of drug administration:

- **What training should be required of providers administering psychedelic therapies in an ambulatory clinic setting?**
- **What competencies do providers need to achieve to serve patients in this phase of care?**

Some specific competencies for the in-clinic day of drug administration are detailed in the Professional Practice Guidelines:

- Guideline 9: Facilitating a safe and therapeutic medication administration session conducted in a comfortable and confidential setting.
- Guideline 10: Monitoring patients for adverse events both during and following the medication administration session and ensuring that complications are addressed. [25]

Our forthcoming competency document, described above under Pre-Administration, will provide further guidance.

- **Should providers be required to have a professional degree (social work, psychologist, other), or not (peers or other trained non-professionals)? Should providers be required to have a medical degree (physician, nurse practitioner, physician assistant, nurse, other)?**

Please see response above, under Pre-Administration.

- **Is there a need for a state licensing requirement for providers?**

As detailed in the Professional Practice Guidelines (Guideline 1), practitioners of psychedelic therapy should be in good standing with the licensure and/or certification requirements of their respective professional disciplines.[26] Licensure addresses competencies, education, ethical and other standards to maintain quality of care and provider accountability.

Given that providers will already possess relevant professional licensure (e.g. MD, LCSW-C, NP or otherwise), additional state licensure requirements are likely unnecessary. New state licensure requirements specific to psychedelics could create significant burdens for clinicians and can complicate the delivery of telehealth services. The lack of reciprocity among states, combined with the complex and duplicative requirements of state-by-state licensing, has historically created substantial operational burdens for clinicians and organizations seeking to do telehealth or provide care across state lines.

- **Is telehealth and/or remote monitoring an acceptable means of caring for patients during drug administration and observation in clinic?**

With regard to participant observation on the day of treatment, *on-site* video monitoring has successfully been combined with in-person monitoring in multiple Phase III clinical trials of

[25] "Professional Practice Guidelines for Psychedelic-Assisted Therapy," *supra.*
[26] "Professional Practice Guidelines for Psychedelic-Assisted Therapy," *supra.*

psychedelics. We expect this model to be successful in clinical practice as well, and an important way to ensure scalability of treatment and thereby narrow disparities in access to care.

Post-administration follow up:

- **What training should be required of providers caring for patients in follow up of psychedelic administration in the days and weeks that follow?**
- **Should providers have specialized training in evidence-based psychotherapy keyed to the specific intervention administered?**

In the post-administration or integration phase, providers should support patients in understanding and making meaning of their psychedelic medication experience and incorporating desired changes into their lives (Guideline 11).[27] While the integration process is largely patient-directed, providers can currently rely on a range of therapy protocols and manuals.[28]

We recommend follow-up counseling as well as in-reach following psychedelic therapy for individuals without adequate support systems. Anecdotes shared with MHA have pointed to difficulty managing symptoms and side effects without a high level of support for some individuals. In addition, we support the use of appropriate measures to track clinical outcomes over time, including the assessment of any side effects or complications.

Our forthcoming competency document, described above under Pre-Administration, will provide further guidance.

- **Should providers be required to have a professional degree (social work, psychologist, other), or not (peers or other trained non-professionals)?**
- **Should providers be required to have a medical degree (physician, nurse practitioner, physician assistant, nurse, other)?**

Please see response above, under Pre-Administration.

- **Is telehealth an appropriate means of conducting follow-up?**

Please see response above, under Pre-Administration.

RFI Section 2: Federally Qualified Health Centers, Certified Community Behavioral Health Clinics, Rural Health Clinics, And Other Ambulatory Clinic Settings

We strongly support HRSA's goal of supporting federally-qualified health center (FQHCs), Certified Community Behavioral Health Clinics (CCBHCs), Rural Health Clinics (RHCs), and other ambulatory safety net providers in the provision of psychedelic therapy. These community-based clinics already serve as trusted sources of integrated care that are culturally and

[27] "Professional Practice Guidelines for Psychedelic-Assisted Therapy," *supra.*
[28] "Professional Practice Guidelines for Psychedelic-Assisted Therapy," *supra.*

geographically accessible to patients. In 2025, approximately 1,400 HRSA-supported FQHCs[29] collectively served more than 32.7 million people, including 25 million uninsured, Medicaid, and Medicare patients; 1 in 5 rural residents; more than 1 in 15 patients 65 or older; and 414,000 Veterans.[30] Meanwhile, over 5,600 rural health clinics provide accessible care to patients in underserved or healthcare-shortage rural areas across the country.[31]

Certified Community Behavioral Health Clinics (CCBHCs) are particularly well prepared to provide psychedelic therapy. There are over 500 CCBHCs across 46 states plus Washington DC and Puerto Rico,[32] providing comprehensive mental health and substance use services to an estimated 3 million people nationwide.[33] Certification requirements include 24/7 crisis response capacity, care coordination agreements with primary care and other partners, and a management team that includes a psychiatrist as a Medical Director.[34] These requirements, along with the clinics' experience in comprehensive behavioral health services, make CCBHCs a very promising locus for scaling access to psychedelic therapy for behavioral health indications. With support from SAMHSA, the National Council for Mental Wellbeing operates the Certified Community Behavioral Health Clinic Expansion Grantee National Training and Technical Assistance Center, an important path for supporting CCBHCs in integration of evidence-based treatments.[35]

In addition to adequate reimbursement (discussed further below), HRSA should invest in both grant funding and technical assistance to support the integration of new psychedelic services at FQHCs, RHCs, CCBHCs, and other ambulatory safety net providers. HRSA has a history of support for the integration of a range of novel treatments and interventions at funded centers, such as pre-exposure prophylaxis for HIV,[36] and, broadly, for behavioral health integration into primary care.[37] HRSA should consider ways to similarly support introduction of psychedelic therapy in safety net clinics through technical assistance. This should include the creation of a training and technical assistance center. We also recommend targeted grant programs for different clinic types to build capacity for service delivery and to ensure ongoing access.

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[29] HRSA, "Find a Health Center." Available at https://findahealthcenter.hrsa.gov/
[30] HRSA, "Impact of the Health Center Program" (Updated July 2026). Available at https://bphc.hrsa.gov/about-health-center-program/impact-health-center-program
[31] Rural Health Information Hub, "Rural Health Clinics (RHCs)" (Updated April 2026). Available at https://www.ruralhealthinfo.org/topics/rural-health-clinics#how-many
[32] The National Council, "Find a CCBHC" (Accessed July 30, 2026). Available at https://www.thenationalcouncil.org/program/ccbhc-success-center/ccbhc-locator/
[33] The National Council, "CCBHC Data and Impact." Available at https://www.thenationalcouncil.org/program/ccbhc-success-center/ccbhc-overview/ccbhc-data-impact/
[34] SAMHSA, "Certified Community Behavioral Health Clinic (CCBHC) CERTIFICATION CRITERIA Updated March 2023" (2023). Available at www.samhsa.gov/sites/default/files/ccbhc-criteria-2023.pdf
[35] National Council for Mental Wellbeing, "CCBHC-E National Training and Technical Assistance Center" (Accessed August 4, 2026). Available at www.thenationalcouncil.org/program/ccbhce-ttac/
[36] HRSA, "BPHC Bulletin: Fiscal Year 2023 Ending the HIV Epidemic - Primary Care HIV Prevention Funding Now Available" (2022). Available at https://content.govdelivery.com/accounts/USHHSHRSA/bulletins/3383eba
[37] NCQA, "NCQA Awarded New HRSA Task Order to Expand Access to Patient-Centered and Behavioral Health Care" (2025). Available at https://www.ncqa.org/news/ncqa-awarded-new-hrsa-task-order-to-expand-access-to-patient-centered-and-behavioral-health-care/

To expand the reach of training, we recommend that HRSA establish a Project ECHO (Extension for Community Health Outcomes)-style collaborative learning focused on psychedelic therapies. This would advance provider and patient adoption by providing education on current evidence, treatment indications, contraindications, patient selection, and expected outcomes. This tool can also support HRSA to develop timely guidance on administration protocols, safety monitoring, staffing models, workflow design, and follow-up practices. The ECHO model supports sharing implementation tools and lessons learned from organizations like CHCs with experience delivering psychedelic therapies.

- **What should be the basic (essential) requirements for safe administration of psychedelic therapies in ambulatory clinic settings, like health centers?**
- **What are the ideal environmental and situational features desired in a clinic setting to optimize therapeutic outcomes? Which of these features are essential, and which are more "nice to have"?**

The Professional Practice Guidelines recommend that providers facilitate a safe and therapeutic medication administration session conducted in a comfortable and confidential setting (Guideline 9).[38] Most current research protocols use a professional location that is comfortable and relaxing; the location should be secure to prevent interruption, but permit access to emergency services if needed.[39] The forthcoming competency document will contain further information regarding setting management.

- **Should a licensed medical provider (physician, nurse practitioner, physician assistant, etc.) medically evaluate a patient prior to drug administration?**
- **Should a medical provider be available on site during a psychedelic treatment session?**

The Professional Practice Guidelines recommend that patients be comprehensively screened in accordance with existing evidence, guidelines, and clinical judgment (Guideline 6).[40] Medical and psychiatric evaluations would require a licensed medical provider.

The Guidelines also recommend that patients be monitored for adverse events during and following the medication administration session, and that a licensed clinician be available to address any medical complications (Guideline 10).[41]

[38] "Professional Practice Guidelines for Psychedelic-Assisted Therapy," *supra.*
[39] BrainFutures, An Expert-Informed Introduction to the Elements of Psychedelic-Assisted Therapy (2022). Available at https://www.brainfutures.org/wp-content/uploads/2022/10/An-Expert-Informed-Introduction-to-the-Elements-of-PAT_web.pdf
[40] "Professional Practice Guidelines for Psychedelic-Assisted Therapy," *supra.*
[41] "Professional Practice Guidelines for Psychedelic-Assisted Therapy," *supra.*

RFI Section 3: Technology-Enabled Scalability

- **Could tools, including AI technology, support patient screening, eligibility determination, risk stratification, or detection of contraindications? What human oversight should be required, and what are the limits of automated screening for this population?**
- **Could AI-enabled monitoring (e.g., automated detection of physiological or behavioral signs of distress) augment or partially substitute for continuous in-person observation during administration, and under what conditions? What safeguards would be essential, recognizing that patients may be acutely vulnerable and unable to self-advocate?**
- **Could AI-supported tools (e.g., integration aids, symptom tracking, conversational support) extend clinician-led follow up and integration?**

Emerging AI-based and other digital technologies that could be relevant to psychedelic therapy are in early phases of development. We support further testing and research to identify if there are appropriate applications of these technologies to psychedelic therapy and to identify and mitigate associated risks and limitations. HRSA and partner agencies at HHS, such as the Center for Medicare and Medicaid Innovation, could consider assessing these tools' validity by integrating them into existing and future pilots.

- **Which technology-enabled models offer the greatest potential to expand access in health centers, Certified Community Behavioral Health Clinics, and Rural Health Clinics while maintaining safety, and could they widen or narrow existing disparities?**

As discussed earlier, on-site video monitoring has successfully been combined with in-person monitoring in multiple Phase 3 clinical trials of psychedelics, and telehealth may be a useful modality for pre- and post-administration for certain patients.

Note Regarding Reimbursement

Adequate reimbursement in both the public and private insurance sectors is vital to scaling psychedelic therapy. We recognize that HRSA does not play a direct role in public or private reimbursement policies, but the agency can support providers and clinics in navigating this new reimbursement realm. For example, HRSA can collaborate with CMS and other payers to develop clear guidance on reimbursement and billing as part of workforce capacity building.

BrainFutures has developed two resources to help pave the way for reimbursement of psychedelic therapy. The *Guide to CPT and HCPCS Codes for Psychedelic-Assisted Therapy* was developed to advance third-party reimbursement, support the utilization of existing codes and the adoption of new codes as needed, provide coding guidance for practitioners, and facilitate communication between practitioners and payers.[42] A separate brief on the intersection

[42] BrainFutures, "A Guide to CPT and HCPCS Codes for Psychedelic-Assisted Therapy" (2025). Available at https://www.brainfutures.org/wp-content/uploads/2025/04/A-Guide-to-CPT-and-HCPCS-Codes-for-Psychedelic-Assisted-Therapy_BrainFutures.pdf

of reimbursement for psychedelic therapy with the Mental Health Parity and Addiction Equity Act (MHPAEA) highlights challenges and opportunities for federal and state enforcement.[43]

Conclusion

With potential FDA approval on the horizon, we are at a crucial time for psychedelic therapy. Collaborative planning and preparation will lay the groundwork for safe and effective access to these important treatments. BrainFutures, Mental Health America, the National Council for Mental Wellbeing and the Meadows Mental Health Policy Institute stand ready to collaborate with HRSA as the agency proceeds with this important work.

If you have any questions, please contact Sarah Norman, Executive Director of BrainFutures, at snorman@brainfutures.org.

Sincerely,

BrainFutures
Mental Health America
National Council for Mental Wellbeing
Meadows Mental Health Policy Institute

[43] BrainFutures, "A Path Toward Parity: Ensuring Equitable Access to Psychedelic-Assisted Therapy" (2024). Available at https://www.brainfutures.org/wp-content/uploads/2024/04/A-Path-Toward-Parity.pdf