

October 5, 2026

Mr. Kyle Diamantis
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993
Submitted via www.regulations.gov

Re: “Considerations for Potential Future Therapeutic Use of Psychedelic Drugs” (Docket No. FDA-2026-N-7542)

Dear Acting Commissioner Diamantis:

On behalf of BrainFutures, Meadows Mental Health Policy Institute, Mental Health America, and the National Council for Mental Wellbeing, thank you for the opportunity to respond to the Federal Register notice regarding Considerations for Potential Future Therapeutic Use of Psychedelic Drugs.

As data from the Substance Abuse and Mental Health Services Administration (SAMHSA) 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 age 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.

Our comments draw from the Professional Practice Guidelines for Psychedelic-Assisted Therapy, published in 2023 by BrainFutures and the American Psychedelic Practitioners Association,² and other sources as indicated. Developed by expert researchers and clinicians, the Professional

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

² 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>

Practice Guidelines aim to support mental health providers in delivering psychedelic treatment that is integrated with therapy during the same treatment episode.³ The Guidelines will be updated in 2027 to reflect the growing body of clinical and implementation evidence for psychedelic therapy.

In addition, a multidisciplinary expert group is in the process of developing [core competencies](#) that will provide a consistent baseline for training programs and a benchmark for evaluating practitioners' ability to safely and effectively deliver psychedelic therapy. The competencies will be available by January 2027.

Based on those documents and processes and our collective expertise in this area, our comments respond to three areas of interest identified in the hearing notice: (1) provider training and credentialing, (2) promotion of patient safety, and (3) considerations for access. In each section, we list the specific issues on which FDA requests information in bold, with our responses following.

We recognize that some of these questions fall outside of the FDA's scope, and many of our recommendations are traditionally addressed by states and professional associations rather than federal entities. Our responses aim to address a wide range of topics.

About the Organizations

BrainFutures is a national non-profit organization 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, policymakers, and funders 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.

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.

³ *Id.*

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.

Founded in 1969, **the National Council for Mental Wellbeing** is the leading membership organization driving policy, practice and system change on behalf of more than 3,200 mental health and substance use treatment organizations serving over 15 million people nationwide. Through advocacy, capacity building and Mental Health First Aid (MHFA), which has trained more than 5 million people in the U.S., the National Council advances access to high-quality care and promotes mental wellbeing as a fundamental part of health and well-being.

General Comments

In this letter, we use the term psychedelic therapy to describe a continuum of clinical services that includes:

- federally regulated psychedelic medications,
- assessment and screening,
- preparation psychotherapy and psychoeducation,
- medication administration and monitoring,
- integration psychotherapy and follow-up,
- care coordination, and
- related support services.

Psychedelic therapy is a model of care that is characterized by the combination of the biological effects of a psychedelic drug with psychosocial interventions such as psychological support, psychotherapy, and other wraparound support, where appropriate.

Although late-phase clinical trials of psychedelic drugs do not always include psychotherapy as part of the treatment protocol, there is substantial evidence that treatment plans which include

both medication(s) and psychotherapy are more effective for treating a range of behavioral health conditions compared to medication or psychotherapy alone.^{4,5}

While the recommendations we make in this letter apply generally to psychedelic therapy, the category of “psychedelics” reflects a class of psychoactive substances with significant variation in compounds, delivery mode, and effects. Training and treatment 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.⁶ 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.⁷ Provider trainings and treatment protocols must be adaptable to meet the needs of patients with different diagnoses. Our comments focus on psychedelic therapies for behavioral health conditions.

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 mental 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 types and levels of support.

I. Provider Training and Credentialing

An interdisciplinary workforce of trained providers will be essential to meet the anticipated demand for psychedelic treatments. As detailed in the Professional Practice Guidelines, training

⁴ Practice Guideline for the Treatment of Patients With Major Depressive Disorder, Third Edition. Available at https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf <https://www.healthquality.va.gov/HEALTHQUALITY/guidelines/MH/mdd/VADODMDDCPGFinal508.pdf>

⁵ Kamenov K, Twomey C, Cabello M, Prina AM, Ayuso-Mateos JL. The efficacy of psychotherapy, pharmacotherapy and their combination on functioning and quality of life in depression: a meta-analysis. *Psychol Med*. 2017 Feb;47(3):414-425. doi: 10.1017/S0033291716002774. Epub 2016 Oct 26. PMID: 27780478; PMCID: PMC5244449. Available at <https://pmc.ncbi.nlm.nih.gov/articles/PMC5244449/>

⁶ Psychedelic Alpha, Psychedelic Drug Development Tracker (Accessed July 30, 2026). Available at <https://psychedelicalpha.com/resources/psychedelic-drug-development-tracker/>

⁷ *Id.*

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).

The evidence base for training and educational curricula, and the expert body(ies), if any, that would be expected to develop, review, or endorse them.

As noted above, 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 a variety of stakeholders, including professional organizations, psychedelic therapy training organizations, academic institutions, government agencies, and drug developers. Workgroup members will discuss 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, New York University, and the University of California, clinical leaders from Sana Health and Radial, a federal liaison from the Department of Health and Human Services (HHS); and a consumer representative who participated in a clinical trial. A representative from the Veterans Health Administration (VHA) is also expected to join the workgroup.

We anticipate that the competencies will address 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 January 2027. These interdisciplinary core competencies will address many of the questions asked in this RFI. Accordingly, we will share the final product with FDA at that time.

Personnel and training needs by phase of care (screening and preparation, administration and monitoring, and follow-up), including minimum staffing during administration and monitoring and the roles and qualifications of non-prescriber personnel such as licensed counselors and peer support specialists.

Competencies by phase of care:

Psychedelic therapy can be provided by a multidisciplinary team with scopes of practice that vary based on the team and on state laws. The Professional Practice Guidelines outline specific competencies applicable to each phase of care. These include:

Pre-administration:

- Obtaining and documenting informed consent before commencing treatment, respecting the patient’s right to withdraw consent, 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 therapeutic 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

⁸ “Professional Practice Guidelines for Psychedelic-Assisted Therapy,” *supra*.

Administration and monitoring:

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

Post-administration and follow-up phase:

- Supporting patients in understanding and making meaning of their psychedelic medication experience and incorporating desired changes into their lives (Guideline 11).¹⁰ While the integration process is often patient-directed, providers can currently rely on a range of psychotherapy protocols and manuals.¹¹

Our forthcoming competency document will provide additional guidance across all phases of treatment.

Minimum staffing and monitoring

Certain elements of psychedelic treatment require licensed clinical providers. The Professional Practice Guidelines recommend that patients be comprehensively screened in accordance with existing evidence, guidelines, and clinical judgment (Guideline 6).¹² Medical and psychiatric evaluations, for example, require a licensed healthcare 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 or psychological complications (Guideline 10).¹³

With regard to participant observation on the day of treatment, on-site monitoring is necessary to support safety. In addition, on-site video monitoring has successfully been combined with in-person monitoring in multiple Phase III clinical trials of psychedelics. We expect this model to be successful in clinical practice as well for treatments where trials have established its safety. Where applicable, this hybrid approach can be an important way to ensure scalability of treatment and thereby narrow disparities in access to care.

⁹ “Professional Practice Guidelines for Psychedelic-Assisted Therapy,” *supra*.

¹⁰ “Professional Practice Guidelines for Psychedelic-Assisted Therapy,” *supra*.

¹¹ “Professional Practice Guidelines for Psychedelic-Assisted Therapy,” *supra*.

¹² “Professional Practice Guidelines for Psychedelic-Assisted Therapy,” *supra*.

¹³ “Professional Practice Guidelines for Psychedelic-Assisted Therapy,” *supra*.

Roles and qualifications of non-prescriber personnel

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.¹⁴

Nonclinical peer support professionals and other unlicensed support staff can play important roles in many behavioral health settings and care teams. With supervision, trained peers can be incorporated into psychedelic treatments and care teams where they can monitor medication sessions and provide support for 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.¹⁵

Integration of peer support and other unlicensed staff within psychedelic therapy care teams will be crucial for ensuring access, especially given the existing shortage of behavioral health professionals across the country. As of June 2026, the Health Resources and Services Administration's (HRSA) workforce data indicates that over 157 million individuals live in areas designated as Mental Health Professional Shortage Areas.¹⁶ 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.¹⁷ The National Council for Mental Wellbeing, for example, advances peer support through specialized training, white papers,¹⁸ and resources like Whole Action

¹⁴ “Professional Practice Guidelines for Psychedelic-Assisted Therapy,” *supra*.

¹⁵ 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). Available at https://www.healthworkforceta.org/wp-content/uploads/2023/07/BHWRC_Peers-in-the-Behavioral-Health-Workforce.pdf

¹⁶ Designated Health Professional Shortage Areas Statistics. Health Resources & Services Administration. June 2026. Available at <https://data.hrsa.gov/default/generatehpsaquarterlyreport>

¹⁷ 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

¹⁸ 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/>;

Management¹⁹ 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 care teams.

Additionally, several federal agencies offer guidance and support on integrating peer support services in care settings. HRSA funds technical assistance for training and certification of peer specialists through its Behavioral Health Workforce Education and Training paraprofessionals program. SAMHSA 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 (CMS) has published guidance to states²⁰ and providers^{21,22} to increase the availability of peer support services in various clinical and non-clinical settings. This complementary interagency work should be leveraged to ensure behavioral healthcare settings appropriately integrate peer services, including for delivery of psychedelic therapies.

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. Evidence shows that justice-involved peer support workers (and community health workers) increase patient engagement.²³ However, certain state codes prohibit certification of peer specialists for work in clinical settings when a history of substance use criminal offenses is present.²⁴ 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.

¹⁹ The National Council for Mental Wellbeing, “Whole Health Action Management.” Available at <https://www.thenationalcouncil.org/service/whole-health-action-management/>

²⁰ 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>

²¹ 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>

²² 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>

²³ 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/>

²⁴ 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).

Training for care coordination across primary care, behavioral health, and specialty providers.

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). 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 streamline care 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 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).

Credentialing and licensure considerations, ranging from background education and experiential qualifications to supervision and practice hour requirements.

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. Licensure addresses competencies, education, ethical and other standards to maintain quality of care and provider accountability.

Given that care team members will already possess relevant professional licensure (e.g. MD, LCSW-C, NP, CPS or otherwise), additional state licensure requirements are likely unnecessary. New state licensure or certification requirements specific to psychedelics could create significant burdens for clinicians and could complicate the delivery of telehealth services (see further discussion below of telehealth services within psychedelic treatment). 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 provide telehealth services or provide care across state lines.

Clinicians should operate within their scope of practice and seek training and consultation opportunities, including accredited continuing medical education or continuing education units, to ensure that they are practicing psychedelic therapy as part of an interdisciplinary team. BrainFutures’ forthcoming core competencies for psychedelic therapy will provide a framework by which clinicians and employers can evaluate competency. This approach recognizes that there are many ways to achieve competency, while new licensures or certifications may unnecessarily restrict patient access by restricting the provider pipeline.

II. Promotion of Patient Safety

Best practices to promote patient safety, including patient education and counseling, assessment of side effects, and considerations of set and setting (*i.e.*, mindset and environment).

Patient education and counseling

The Guidelines provide detailed recommendations regarding patient education and counseling/psychotherapy, including obtaining and documenting informed consent that addresses all relevant elements of therapy before commencing treatment (Guidelines 4 and 5); building rapport and trust with patients during the preparatory period (Guideline 7); and 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).²⁵ Patients should be offered psychotherapy from a licensed therapist both before and after medication administration to ensure the patient is adequately prepared for the experience, that treatment benefits are maximized, and treatment-emergent adverse events are identified and managed (in collaboration with other members of the care team).

Assessment of side effects

The Guidelines urge monitoring patients for adverse events both during and following the medication administration session and ensuring that complications are addressed (Guideline

²⁵ “Professional Practice Guidelines for Psychedelic-Assisted Therapy,” *supra*.

10).²⁶ This may require participation from multiple members of the care team or coordination with additional providers who are not directly involved in the provision of psychedelic care. Additional research is needed to better understand the frequency and type of contact with patients that is required to identify and manage adverse events that may emerge in the days or weeks after medication administration. Forthcoming core competencies will also provide additional information on monitoring for and managing both physiological and psychological side effects.

Set and setting:

The Guidelines recommend that providers facilitate a safe and therapeutic medication administration session conducted in a comfortable and confidential setting (Guideline 9).²⁷ 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.²⁸

The forthcoming competency document will contain further information across these topics.

Topics that should be explicitly addressed in informed consent procedures, *e.g.*, the potential for an amplified power imbalance between patient and provider, the use of therapeutic touch, and the risk of psychological distress or a challenging psychedelic experience.

Guideline 4 addresses 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 therapeutic touch (Guidelines 4 and 5).

The forthcoming competency document will contain further information regarding informed consent.

Recommended practices to screen patients before treatment for medical and psychiatric conditions associated with greater risk of adverse outcomes (*e.g.*, cardiovascular disease, psychosis, or suicidality).

²⁶ “Professional Practice Guidelines for Psychedelic-Assisted Therapy,” *supra*.

²⁷ “Professional Practice Guidelines for Psychedelic-Assisted Therapy,” *supra*.

²⁸ 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

The Guidelines address ensuring that patients have been comprehensively screened in accordance with existing evidence, guidelines, and clinical judgment (Guideline 6). Medical and psychiatric evaluations require a licensed medical provider. Specific screening protocols must be tailored to the approved medication and should weigh the risk of treatment against the risk of foregoing treatment.

The forthcoming competency document will contain further information.

Mechanisms to prevent, detect, and report ethical violations by practitioners to appropriate authorities.

The competencies project will address the domain of Ethics and Boundaries. Practitioners will also remain responsible for meeting ethical requirements within their respective professions.

Criteria for determining appropriate monitoring during and after drug administration, as well as coordination of post-administration follow-up, including with emergency and crisis response services where needed.

Guideline 10 emphasizes the importance of monitoring individuals for adverse events during the dosing session and in the period that follows, and ensuring that any emerging complications are promptly managed. During the post-administration phase—or the integration stage—clinicians should help patients process their psychedelic experience, draw insight from it, and translate those insights into meaningful life changes (Guideline 11). Although integration work is often shaped by patient priorities, clinicians can draw on existing therapeutic models, manuals, and structured approaches.

Programs must also maintain clear operational protocols to identify and respond to side effects, including pathways for escalation when higher-level care is needed. We recommend routine follow-up counseling for all patients, and proactive outreach for individuals who lack sufficient personal support after psychedelic treatment. Anecdotes shared with MHA highlight that some patients struggle to manage symptoms or side effects without robust support systems.

Finally, we endorse the use of measurement-based care and related frameworks to track clinical outcomes over time, including the systematic assessment of side effects and complications.

III. Considerations for Access

Evidence needs for coverage, benefit design, reimbursement, and payment models, including healthcare economic impact analyses.

Preparation and coordination between providers and payors to enable appropriate access to services.

Adequate reimbursement in both the public and private insurance sectors is vital to scaling psychedelic therapy.

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.²⁹ As noted in this Guide, CPT III codes are particularly important and should be used to support consistent implementation of psychedelic-assisted therapies. CPT III codes are specifically designed for emerging clinical interventions that require structured data collection before permanent valuation. Their use builds a foundation for a uniform billing pathway across payers and care settings, reducing administrative variability and preventing the proliferation of proprietary or inconsistent coding practices.

Consistent use of CPT III codes also enables transparent claims processing and creates a reliable national dataset on utilization, safety events, staffing patterns, and resource needs. This information is essential for evaluating outcomes, informing future RVU assignment, and determining whether the service should transition to Category I status.

A separate brief on the intersection of reimbursement for psychedelic therapy with the Mental Health Parity and Addiction Equity Act (MHPAEA) highlights challenges and opportunities for federal and state enforcement. Payers must ensure compliance with MHPAEA.³⁰

In implementation of reimbursement policies, it is important to note that:

- Drugs are not experimental once given an FDA approval for a particular indication. Evidence needs for coverage must not create barriers or requirements that are more restrictive than those in place for comparable medical or surgical interventions.
- Psychotherapy is already standard and paid for almost universally for all the conditions in the Phase 3 pipeline.
- Payers should utilize the CPT III code to ensure consistent, transparent billing processes.

²⁹ A Guide to CPT and HCPCS Codes for Psychedelic-Assisted Therapy. BrainFutures. Available at https://www.brainfutures.org/wp-content/uploads/2025/04/A-Guide-to-CPT-and-HCPCS-Codes-for-Psychedelic-Assisted-Therapy_BrainFutures.pdf

³⁰ A Path Toward Parity: Ensuring Equitable Access to Psychedelic-Assisted Therapy, BrainFutures. Available at <https://www.brainfutures.org/wp-content/uploads/2024/04/A-Path-Toward-Parity.pdf>

Telehealth screening, follow-up, and care coordination.

Telehealth has become an established and important modality for behavioral health care, supported by a range of resources and practice guidelines.³¹ 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 importance of telehealth access even outside the pandemic context for underserved and rural communities.³² The National Council for Mental Wellbeing has developed a video series to support effective, client-centered telehealth in behavioral health settings.³³ 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 where clinically appropriate during the screening, preparation, and integration/follow-up phases of care. Psychotherapy delivered via telehealth is well-established in contemporary clinical practice and should be available to psychedelic therapy patients as part of the overall treatment plan, depending on individual presentation or complexity. Updated Professional Practice Guidelines will address the appropriate use of telehealth across stages of the process.

Conclusion

At this critical juncture for psychedelic treatment, it is vitally important that FDA and other stakeholders proceed based on evidence and expert consensus to appropriately address patient safety and support equitable access. BrainFutures, Meadows Mental Health Policy Institute,

³¹ 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

³² 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

³³ 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/>

Mental Health America, and the National Council for Mental Wellbeing stand ready to collaborate with FDA 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

Meadows Mental Health Policy Institute

Mental Health America

National Council for Mental Wellbeing