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Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Submitted electronically to www.regulations.gov

> **RE: FR Doc. 2026-14146; Request for Information, Training and Care Delivery Models for Safe Administration of Potential FDA-Approved Psychedelic Therapies in Ambulatory Clinical Settings**

The Psychedelic Mental Health Access Alliance (PMHA Alliance) appreciates the opportunity to respond to HRSA's request for information on training and care delivery models for the safe administration of potential FDA-approved psychedelic therapies in ambulatory clinical settings.

We want to begin by commending several choices HRSA has made in framing this RFI. Centering Federally Qualified Health Centers, Certified Community Behavioral Health Clinics, and Rural Health Clinics is the right starting point. These are where underserved patients already get behavioral health care, and where safe and appropriate access is critical to ensure. Disaggregating workforce training into pre-administration, day-of-administration, and post-administration phases reflects the operational reality that these phases carry different competency and staffing requirements. Asking which environmental features are essential, and which are optional invites evidence rather than the wholesale import of clinical trial conventions. Understanding how implementation would affect workforce productivity and clinic capacity recognizes that a delivery model that is safe but operationally unsustainable is not, in practice, accessible. Exploring whether technology-enabled models could widen or narrow disparities is precisely the question that determines whether these therapies reach underserved communities or bypass them.

The PMHA Alliance is a national nonprofit initiative working to build the bridge between psychedelic-assisted therapy (PAT) and health systems for underserved populations. We are dedicated to developing Medicaid-focused, community-informed psychedelic therapy models of care that are ethical, inclusive, and effective. These models of care must be affordable, leverage existing available workforce, and integrate into the existing community-based services and organizations serving people from low-income and underserved communities.

Our work centers on a multi-state evidence generation strategy focused on Medicaid and underserved populations with health-related social needs. We are currently conducting a community-informed safety and feasibility pilot of group psilocybin-assisted therapy for PTSD in New Mexico, in partnership with the University of New Mexico School of Medicine's Department of Family and Community Medicine. The pilot prioritizes Indigenous community members, survivors of sexual trauma, veterans, and first responders and is designed to generate practical evidence about how group-based psychedelic-assisted care can be delivered safely and feasibly within existing health systems.

In New Jersey, we are beginning our second study in partnership with the Camden Coalition, starting with a 12-month community engagement and co-design process that will directly inform the design of the study. PMHA Alliance and the Camden Coalition also co-designed the EASE Tool (Ecosystem Alignment for Sustainable Expansion),

a framework based on the Coalition's Community Ecosystem Alignment Tool. This tool is designed to help communities of care integrate psychedelic-assisted therapy for populations with complex care needs. The Camden Coalition will actively use the EASE Tool in New Jersey as it develops its psychedelic-assisted therapy programming.

We have completed a Delphi consensus process with McGill University producing a universal variable set for PAT delivery, scheduled to be finalized by September 2026. We also worked with the Center for Health Care Strategies (CHCS) on an analysis of what state Medicaid agencies, health plans, and safety-net providers will need to cover and deliver these therapies, informed by interviews with Medicaid officials, managed care plans, and community-based providers. This report will be available in late August 2026, and we will submit it to HRSA for the record as soon as it is released.

Our comments address workforce training and development, group-based care delivery, and the cost and implementation data HRSA will need to inform requirements that safety-net providers can meet while ensuring equitable, safe, and effective access to psychedelic-assisted therapies.

I. Workforce Training and Development

The psychedelic workforce is still emerging, and many questions regarding optimal training standards, scopes of practice, supervision, and workforce composition remain unresolved. Specific training requirements will necessarily vary according to the therapeutic agent, indication, mode of administration, patient population, and eventual FDA requirements. Rather than prematurely establishing a single workforce model, HRSA has an opportunity to create a flexible framework that supports continued learning while establishing strong standards for safety and quality. Based on PMHA Alliance's work developing and testing access-oriented approaches to psychedelic-assisted care within public and community health contexts, we recommend that HRSA consider the following principles.

1. Develop a Tiered, Competency-Based Workforce Model

Psychedelic-assisted care should not be built around the assumption that every member of the care team must hold the same credentials or perform the same functions. Medical screening, diagnosis, preparation, medication administration, therapeutic support, monitoring, integration, peer support, care navigation, and longitudinal follow-up require different competencies and levels of clinical responsibility. HRSA should support a **tiered, competency-based workforce framework in which education, credentialing, supervision, and training requirements are matched to the functions being performed and the level of clinical risk involved.** Such a framework could enable licensed clinicians, appropriately trained psychedelic facilitators, peers, community health workers, and other trained personnel to work within clearly defined scopes as part of interdisciplinary care teams.

PMHA Alliance's emerging care team models emphasize **interdisciplinary and integrative team structures** in which care is delivered through a **mix of licensed clinical providers and certified or trained non-clinical facilitators, particularly peer facilitators trained in psychedelic-assisted facilitation.** These peer facilitators can play a critical role in preparation, presence support, integration, and continuity of care, working in collaboration with licensed clinicians who provide medical oversight, diagnostic evaluation, and clinical risk management. This blended model reflects real-world implementation needs in public mental health systems, protects patient safety, and mitigates constraints on access, particularly in rural, safety-net, and medically underserved communities.

2. Establish Core Competencies While Allowing Training to Be Adapted to Populations and Settings

HRSA should establish a common foundation of competencies while allowing additional training requirements to reflect the populations and settings in which care is delivered. Core competencies may include psychedelic pharmacology and safety; ethics and professional boundaries; preparation; altered-state support; recognition and escalation of adverse events; trauma-informed care; integration principles; cultural humility; interdisciplinary collaboration; and appropriate documentation and continuity of care.

Psychedelic competency alone, however, is not sufficient preparation for every population. Providers serving veterans and first responders, survivors of sexual trauma, Tribal and Indigenous communities, people with serious mental illness, or other populations may require additional training specific to the histories, needs, risks, cultural contexts, and lived experiences of those communities. HRSA should therefore pursue a framework that **standardizes essential competencies while allowing training to be contextualized for specific populations and care environments.**

3. Include Simulation, Observed Practice, and Supervised Learning in Workforce Development

Psychedelic-assisted care requires relational, ethical, and situational competencies that cannot be adequately developed or assessed through didactic education alone. HRSA should encourage workforce-development models that combine **didactic education → simulation and scenario-based learning → observed practice → supervised clinical or facilitation experience → ongoing consultation and continuing education.**

Simulation is particularly valuable for preparing providers to respond to complex situations before encountering them with patients—intense emotional experiences, trauma activation, boundary challenges, psychological distress, and situations requiring escalation to higher levels of clinical care. Emerging technologies, including virtual standardized patients and carefully designed AI-supported simulation tools, may also expand access to high-quality training and provide repeatable opportunities to practice difficult scenarios.

As one emerging example, PMHA Alliance has partnered with Fireside Project, a nonprofit psychedelic harm-reduction organization, to co-develop and test a series of AI-supported simulations using Lucy, Fireside Project's interactive, voice-based psychedelic support simulation tool. The scenarios were designed around challenging experiences that could arise in **group psychedelic-assisted therapy settings**, letting care team members practice communication, relational judgment, and group dynamics in a lower-risk environment. This work is in the early stages, and such approaches should supplement rather than replace human supervision, mentorship, and evaluation. The training model is described in our published study protocol.

4. Intentionally Develop Peer and Community-Based Workforce Pathways

A scalable psychedelic workforce should extend beyond traditional licensed behavioral health professionals. HRSA should support the thoughtful inclusion of appropriately trained **peer support specialists, community health workers, navigators, and other community-based personnel** within psychedelic care teams, with clearly defined roles, competencies, supervision structures, and escalation protocols.

These workforce members contribute expertise distinct from clinical expertise—lived experience, cultural knowledge, community trust, navigation support, and continuity of care—which matters especially for communities that have historically experienced barriers to or mistrust of traditional mental health systems. Developing these pathways should not simply be viewed as a strategy for reducing labor costs. Peer and community participation is an

important component of building care models that are culturally responsive, community-connected, and capable of supporting patients before and after time-limited clinical interventions.

5. Treat Workforce Development as Essential Implementation Infrastructure

Requiring specialized training without simultaneously investing in the infrastructure necessary to obtain it could create significant barriers to adoption within publicly funded and safety-net systems. Health centers, CCBHCs, Rural Health Clinics, community mental health organizations, Tribal health systems, and other safety-net providers may have limited capacity to absorb the cost of specialized training, protected staff time, supervision, practicums, and continuing education. Our work with CHCS points to the same conclusion from the payer side: coverage of a new therapy does not by itself produce provider participation, and building provider capacity through training and ongoing support is a precondition for adoption in the safety net.

HRSA should therefore consider workforce development an essential component of implementation infrastructure and explore mechanisms to support:

- paid training and protected staff time;
- scholarships and training stipends;
- supervised practicum opportunities;
- train-the-trainer models;
- continuing education and consultation;
- peer and community workforce development;
- technical assistance for safety-net organizations; and
- partnerships among health systems, training organizations, academic institutions, and community-based organizations.

Workforce policy should also be developed alongside sustainable payment policy. What safety-net organizations can offer is shaped greatly by what their payment structures support. A workforce model described without a corresponding path to sustainable payment for the full care team will be adopted only by organizations that can absorb the difference.

Taken together, these principles reflect a single view. The central workforce question is not only who is qualified to provide psychedelic-assisted care, but **what combination of people, competencies, training, supervision, and infrastructure will allow this care to be delivered safely and sustainably within the systems that serve medically underserved communities.** We recommend that federal workforce development efforts prioritize **competency over professional title alone; interdisciplinary and tiered care teams; population- and setting-specific preparation; experiential and supervised learning; meaningful roles for peers and community-based workers; and dedicated investment in workforce infrastructure.**

II. HRSA Should Explicitly Consider Group-Based Delivery Models

HRSA should consider group-based delivery in any guidance it develops, because it speaks directly to questions raised in this RFI: how many trained providers must be physically present per patient, how the care delivery model affects workforce productivity and clinic capacity, and how clinic organization and operations should be adapted.

Each of these turns on the constraint HRSA names under *Technology-enabled scalability* — the labor intensity of psychedelic therapy in communities where workforce shortages are most acute. Group delivery addresses workforce and capacity constraints and is already familiar to safety-net providers. It is also supported by existing empirical data.

Published micro-costing data from two group protocols—an MDMA-assisted group therapy trial for veterans with PTSD at the VA Portland Health Care System and a psilocybin trial for cancer patients with major depressive disorder at Sunstone Therapies — found that group delivery reduced clinician costs by 50.9 percent and 34.7 percent respectively. Overall variable costs also were lower by roughly 20 percent in both, while allowing an additional 29 patients to be served per full-time-equivalent clinician per year. The two protocols are structurally different. One runs most sessions in cohorts of six, with a four-person team pairing one of two doctoral-level psychologists with a nurse practitioner or a veteran peer counselor. The other keeps each patient in a separate room with an individual therapist while a single clinical supervisor monitors three to four patients remotely by closed-circuit television. "Group" therefore describes a range of models, including shared-supervision configurations that preserve individual privacy.

This speaks directly to HRSA's question about provider-to-patient ratios. The two-clinicians-per-patient configuration common in psychedelic trials was adopted to demonstrate maximal safety to regulators; the authors note no evidence that this level of clinician intensity is required for safety or efficacy. We urge HRSA not to treat the trial configuration as the presumptive ambulatory standard absent evidence that it is necessary.

Group models are a particularly good fit for the settings this RFI targets, and our work with CHCS points in the same direction: community-based behavioral health settings are likely to be central access points, settings that already integrate medical and behavioral health services are positioned to use scarce medical provider time efficiently, and group delivery is one of the few available levers for relieving the staffing pressure PAT places on them. Group therapy is established ground in these systems—nearly every state responding to a 2022 Kaiser Family Foundation survey of Medicaid behavioral health coverage reported covering it, though some apply copayments, prior authorization, or annual service caps—and encounter-based payment in health centers and CCBHCs may align well with a bundled PAT episode. The efficiencies extend beyond clinicians to the medical providers required on site during dosing and aftercare and to peers and community health workers, which is the tiered team structure described in Section I.

PMHA Alliance is testing this directly. Our New Mexico pilot is a psilocybin *group* therapy program, co-designed with community members and delivered with wrap-around supports addressing participants' health-related social needs.

We recommend that HRSA name group and shared-supervision delivery models explicitly in any technical assistance or guidance it develops, and that any staffing or provider-presence requirements be written so as not to foreclose them. One important caveat belongs alongside that recommendation: the safety thresholds for group size and clinician-to-patient ratio have not been established, and are likely to vary by indication, compound, and population.

III. HRSA Should Collect Standardized Cost and Implementation Data

The RFI asks respondents to distinguish essential requirements from those that may be optional; whether a licensed medical provider must evaluate patients and remain on site; whether health centers should be required to achieve certification; and what facility, storage, security, and inventory-control requirements would be necessary. Each of

these is simultaneously a safety question and a cost question. A requirement that a physician remain on site for an eight-hour dosing session is a staffing cost; a certification requirement is an administrative cost; treatment-room and storage specifications are capital costs. Yet no section of this RFI asks respondents for cost data, and very little exists for safety-net settings.

The cost evidence that does exist comes largely from clinical trial and specialty settings and centers on direct clinician time. It does not capture what it would actually cost a health center to deliver this care: administrative and overhead burden, staff training and supervision, facility modification, security and inventory control, and the operational effect of dedicating rooms and staff to extended sessions. These are precisely the costs an FQHC or Rural Health Clinic would bear, and they have not been measured in these settings. This is the evidence that would let HRSA write guidance health centers can build to: requirements calibrated to what a safety-net site can staff and resource, and technical assistance that informs a health center what implementing PAT will require.

The experience with esketamine is instructive, and our analysis with CHCS discusses several challenges to address as policymakers and safety-net providers prepare to implement PAT. Coverage alone did not produce access: in the two years following FDA approval, prescribing rates among Medicaid members were low, driven substantially by limited provider participation, with payment rates, certification requirements, and unfamiliarity among the contributing factors. Any FDA approval of a psychedelic drug is likely to carry a risk evaluation and mitigation strategy with provider certification, training, and monitoring requirements attached, and those requirements will shape not only safety but whether providers participate at all. A care model providers cannot afford to deliver will not reach patients regardless of how carefully it is specified.

We recommend that HRSA define a minimum standardized cost and implementation dataset to be collected prospectively wherever these therapies are delivered in HRSA-supported settings, including:

- staffing time and compensation by credential and by phase of care;
- facility and treatment-room utilization;
- storage, security, and inventory-control costs;
- staff training, supervision, and protected-time costs;
- patient time and travel burden, including post-session transportation; and
- total cost per encounter and per completed episode.

PMHA Alliance is already building this evidence. A prospective micro-costing study, conducted by the University of California, Berkeley Collaborative for the Economics of Psychedelics, is embedded in our New Mexico pilot and takes a public-payer perspective. It captures staffing time by role, facility use, training and supervision, administrative overhead, and the participant-enabling supports such as transportation that clinical trial budgets typically omit. It will also produce a standardized costing instrument intended for reuse across community-based sites, which HRSA could draw on directly in developing the dataset described above.

This is consistent with what our work with CHCS has identified as a priority: research that reflects the realities of safety-net delivery, evaluates lower-cost care models including group-based approaches and the integration of peers, and measures the outcomes and costs that payers and providers actually need in order to make coverage and adoption decisions. PMHA Alliance's forthcoming Delphi variable set includes a healthcare delivery domain covering cost breakdown by drug, staffing, facilities, and overhead, along with staffing configuration and care delivery

barriers. We would welcome the opportunity to share it with HRSA in advance of publication, along with findings from our pilots and our CHCS analysis, and to serve as a resource as the agency develops its approach.

We further recommend that HRSA coordinate with CMS so that these data are structured to inform coverage and payment design for FQHCs and CCBHCs, including bundled approaches suited to their encounter-based payment structures. The temporary CPT codes introduced in 2024 for continuous in-person monitoring during psychedelic medication therapy already provide a documentation scaffold this effort could build on. **Finally, we recommend that HRSA treat any initial guidance as provisional**, with a defined mechanism for revisiting and refining it as implementation evidence accumulates. The evidence base is being actively built; guidance issued before it is available risks locking in requirements that real-world data may later show to be either too burdensome for safety-adjacent needs or insufficiently protective in areas that matter more than currently assumed.

IV. Conclusion

Our three recommendations are:

- **Workforce.** Define requirements by function and clinical risk rather than professional title, so that clinicians, trained facilitators, peers, and community health workers can each work within defined scopes.
- **Care delivery.** Consider group and shared-supervision delivery models explicitly and write staffing requirements so as not to foreclose them.
- **Evidence.** Collect standardized cost and implementation data from the settings where this care would be delivered, coordinating with CMS so those data inform coverage and payment design.

These recommendations share a practical aim: guidance that health centers can realistically implement with the staff, space, and resources available to them. Because the evidence needed to inform key aspects of PAT is still being generated, we encourage HRSA to treat initial guidance as provisional.

Designing the PAT workforce and care delivery model intentionally now can help ensure that future psychedelic therapies are not limited to specialized or privately funded settings but become part of an accessible and sustainable public mental health care system.

Thank you for considering our comments, and for the Administration's attention to safe and equitable access to psychedelic-assisted therapies. PMHA welcomes the opportunity for continued engagement and to serve as a resource to HRSA.

Respectfully,

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