REASON FOR HOPE | VETERAN MENTAL HEALTH LEADERSHIP COALITION

From Innovation to Restoration

A National Framework for the Safe, Ethical, and Equitable Delivery of Potential FDA-Approved Psychedelic Therapies

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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

Dear Administrator Engles,

Reason for Hope (RFH) and the Veteran Mental Health Leadership Coalition (VMHLC) appreciate the opportunity to respond to HRSA's request for information regarding workforce training and care delivery models for potential future FDA-approved psychedelic therapies in ambulatory clinical settings.

RFH and VMHLC bring together scientific, clinical, policy, implementation, Veteran, family, and lived-experience perspectives, including more than 50 mission-aligned partner organizations. Our work and supported research directly engage several issues raised by this RFI, including group treatment models, family engagement, peer and community support, and longitudinal care. Appendix A indexes our responses to each question posed in the RFI.

We strongly support HRSA's focus on medically underserved communities. FDA approval, by itself, will not create meaningful access. Whether these therapies reach patients in rural, safety-net, Tribal, and community settings will depend on a competent workforce, sustainable reimbursement, appropriate facilities, ethical safeguards, referral and emergency pathways, and data infrastructure - all without lowering the standard of care.

FDA's July 2026 final guidance emphasizes systematic safety assessment, representative study populations, durability, and clear characterization of the intended treatment model. HRSA's complementary role is to help ensure that, if products are approved, real-world delivery preserves clinically relevant safety and ethical protections while creating feasible and equitable pathways to access. We hope the recommendations that follow help advance that goal.

Executive Vision: Building the Future of Behavioral Health

The United States stands at an inflection point in behavioral healthcare. Psychedelic therapies make several longstanding challenges especially visible: how to translate complex interventions into routine care, distinguish essential safeguards from unnecessary burden, scale without eroding quality, protect people during periods of heightened vulnerability, and ensure that scientific advances reach the communities most in need.

The appropriate national response is neither uncritical enthusiasm nor reflexive restriction. It is responsible stewardship: systems that preserve scientific rigor and patient safety, remain proportionate to demonstrated risk, support equitable access, acknowledge uncertainty, and generate evidence to improve care over time.

The challenge before HRSA is not simply preparing clinicians to administer a new class of therapies. It is preparing healthcare systems to responsibly translate emerging scientific advances into care that is safe, sustainable, equitable, patient-centered, and within reach of the communities that need it most. Much of what this requires - rigorous informed consent, reliable adverse-event reporting, accountable clinical infrastructure, and honest measurement of outcomes - is not specific to psychedelics. Building these capabilities now would strengthen behavioral healthcare well beyond this class of treatments.

That capacity should be built toward a clear end. Restoration - understood broadly to include well-being, functioning, relationships, purpose, identity, autonomy, hope, belonging, community participation, and quality of life - should be a guiding objective. A person may experience meaningful restoration while some symptoms remain; conversely, a symptom score may improve without a corresponding return of connection, purpose, or daily functioning. This orientation does not diminish conventional clinical outcomes. It places symptoms and safety within a fuller account of benefit, harm, durability, equity, and real-world functioning. These outcomes can be assessed through a harmonized core set of validated symptom, functional, well-being, safety, and patient-defined measures, as discussed in Section VII.

Guiding Principles

Principle	Implication
Restoration beyond symptom reduction alone	The ultimate aim is meaningful, durable improvement in how people live, function, connect, and participate in their communities. A harmonized core set of validated clinical, functional, well-being, safety, and patient-defined measures should accompany symptom measures during implementation (Section VII).
Rigor and access must advance together	Underserved communities should receive the same evidence-informed standard of care, with adaptations justified by evidence rather than cost alone (Sections III and VI).
Reasonable fidelity, followed by evidence-based adaptation	Early care should remain aligned with the evidence-supported and FDA-approved model while material adaptations, such as group care delivery, are prospectively evaluated (Section III).
Competency-based, role-appropriate workforce design	Responsibilities should be assigned according to demonstrated competence, licensure, scope of practice, and accountability (Section I).

Principle	Implication
Ethical stewardship is clinical infrastructure	Consent, boundaries, privacy, cultural humility, accountability, and protection from exploitation are operational requirements (Section II).
Technology should augment human care	Digital tools should promote safety, reduce burden, expand continuity, and improve quality without replacing human presence where vulnerability and judgment require it (Section V).
Proportionate, risk-stratified standards	A shared minimum core of infrastructure, staffing, training, and accountability should apply across treatments, with additional requirements calibrated to the product, patient, setting, label, REMS, and demonstrated risks (Sections III and IV).
Continuous learning	Uncertainty should lead to structured measurement and comparative research, not unsupported deregulation or permanent overregulation (Section VII).

I. Restoration Through Safe and Competent Care

HRSA organizes its workforce questions across pre-administration, administration-day, and post-administration phases. The central question is not which profession should own psychedelic care, but which competencies are required at each point, who is legally and clinically accountable, and how those competencies are demonstrated and maintained. Every program should identify in advance the clinician accountable for medical eligibility and prescribing, the clinician responsible during administration, and the clinician or team responsible for continuity and delayed adverse events.

A. Pre-administration screening, evaluation, and preparation

A two-stage process is generally preferable: an initial standardized screen followed by a comprehensive clinical evaluation. Trained clinical staff may conduct initial screening using validated protocols and escalation rules. Final psychiatric and medical eligibility should remain with appropriately licensed clinicians who have access to the relevant record, can obtain consultation, and are authorized to make the required decisions - including prescribing - under federal and state law and consistent with relevant Food and Drug Administration (FDA) product label and Risk Evaluation and Mitigation Strategy (REMS) requirements.

The comprehensive evaluation should be similar to relevant trial eligibility assessments, addressing diagnosis and severity; treatment history; suicidality and self-harm; psychosis, mania, dissociation, cognition, substance use, trauma, and moral injury; relevant medical and cardiovascular risks; medication and supplement interactions; pregnancy considerations when applicable; prior psychedelic exposure; social supports; transportation and discharge; housing stability; informed-consent capacity; and ability to participate in follow-up. Screening should identify not only contraindications but also modifiable risks and supports that may make treatment safer.

Preparation should not be reduced to procedural orientation. Depending on the approved model and individual needs, it may include realistic expectation setting; discussion of uncertainty, potential benefit, nonresponse, and harm; clarification of boundaries and touch; planning for distress, trauma activation,

dissociation, or requests for help; identification of cultural or spiritual preferences; communication plans with existing clinicians and supports; and discharge planning. Telehealth can appropriately support preliminary screening, education, collateral interviews, some preparation, and interdisciplinary review. Whether an evaluation must be in person should depend on the product label, state law, clinical complexity, availability of reliable records and vital signs, and the need for physical examination or testing.

B. Role allocation, licensure, and collaboration

HRSA should support role clarity rather than a single mandatory professional pathway. A practical allocation is as follows:

- Initial standardized screening may be performed by trained clinical staff using validated tools and clear escalation procedures.
- Diagnostic assessment and psychiatric eligibility should be completed by a licensed behavioral health or medical clinician qualified to diagnose and assess relevant risks. Well-trained staff may collect structured histories, administer validated measures, and support the assessment and evaluation under close supervision, but should not independently make decisions that require professional licensure or other legal authority.
- Medical evaluation, medication reconciliation, medical clearance, prescribing, and medication administration should be performed or approved by professionals authorized under federal and state law and consistent with the product label.
- Administration-day psychological support may be provided by licensed clinicians or other specifically trained personnel (e.g., peer support specialists) operating within a defined scope, supervision structure, and escalation plan.
- Psychotherapy should be delivered by appropriately licensed or supervised psychotherapy providers when psychotherapy is part of the approved treatment model. Therapeutic support models could be provided by well-trained staff under close supervision.
- Peers may contribute to navigation, education, engagement, therapeutic and recovery support, and community connection, but should not substitute for diagnosis, medical clearance, prescribing, emergency response, or independently delivered psychotherapy outside their scope.
- Post-administration follow-up should be assigned according to the function performed, with a licensed clinician clearly responsible for clinical escalation and delayed adverse events.

HRSA should not presume that a new standalone state psychedelic-provider license is necessary for every role. Existing professional licensure, scope-of-practice requirements, product-specific competency verification, site credentialing, and federal requirements may be sufficient. A separate licensing category should be considered only where it addresses a defined gap that cannot be managed through existing professional and facility oversight and liability structures.

Programs should use a closed-loop collaboration model: a named coordinating clinician; a shared treatment and emergency plan; clear responsibility for medication changes; consent-based exchange of records; pre-administration case review for complex patients; same-day communication after significant events; written handoffs after administration; and defined responsibility for delayed concerns. Primary care, behavioral health, pharmacy, emergency services, and the administration team should not function as disconnected silos.

C. In-clinic administration and observation

Psychedelic products are not a single operational category. While we anticipate certain shared minimum facility requirements, specific administration and observation requirements will vary based on product label and REMS requirements informed by pharmacology, dose, route, duration, intensity of subjective effects, medical and psychiatric risk, and approved indication.

Administration-day care is not simply medication delivery plus passive observation. Patients may experience panic, dissociation, grief, shame, traumatic memory, confusion, transient disorientation, dependency, medical symptoms, or difficulty communicating needs. Staff must distinguish expected acute effects from clinically significant distress, psychiatric destabilization, or medical emergency, and recognize when supportive noninterference becomes neglect.

The on-site team should collectively demonstrate competence in product-specific knowledge; vital-sign and medical monitoring; behavioral de-escalation; trauma-informed and culturally responsive care; recognition of suicidality, mania, psychosis, severe dissociation, and delirium; emergency response; boundaries and touch; documentation; discharge; and communication with the longitudinal team. Simulation should be used for low-frequency, high-consequence events. A medical clinician with authority and competence to respond to foreseeable complications should be immediately available on site or through a clearly defined alternative that provides equivalent response capability, as supported by the product risk profile, label, and local emergency capacity.

Not all psychological support is psychotherapy, but psychologically competent support is not passive observation. If psychotherapy is part of the approved model, the providers delivering it should meet relevant professional and intervention-specific standards. Staffing ratios should be risk-stratified rather than fixed across all products and patients. No patient should be left without immediate access to human assistance during acute impairment. Video monitoring or recording may provide a critical *additional* safeguard for patients and providers, but should not be treated as a substitute for clinically appropriate human support. Early implementation should be conservative, with prospective evaluation before moving toward higher patient-to-staff ratios, group administration models, or technology-enabled reductions in on-site staffing.

Psychedelic therapies are not simply medications administered in the presence of clinicians. Rather, the available evidence has largely evaluated integrated models in which pharmacologic effects occur within structured therapeutic, relational, and clinical environments designed to promote safety, support, and continuity of care. Depending on the treatment model and patient needs, this continuum may appropriately include professional peer support, family or trusted-support engagement, and community-based recovery resources. For Veterans, existing VA peer-support and Whole Health infrastructure may offer useful models for continuity beyond the administration visit.

D. Post-administration care, family support, and continuity

Post-administration care should include safety follow-up and support for translating the experience into daily life. Safety follow-up should assess sleep, mood, suicidality, mania, psychosis, dissociation, substance use, impulsive decisions, medical concerns, and functional deterioration. Integration may involve reflection, behavior change, relapse prevention, relationships, and connection to evidence-based psychotherapy or other services.

As noted above, for the Veteran community, incorporation with complementary tools through the VA's existing Whole Health initiative could prove critical for long-term restoration. We encourage HRSA to support similar evidence-based integration tools for patients in non-VA community settings that can improve durability of response, overall wellness, and long-term recovery.

Providers should support meaning-making without prescribing meaning. Patients must be free to interpret, or decline to interpret, their experiences in psychological, biological, cultural, spiritual, religious, or other terms. Clinicians should not impose metaphysical explanations, personal ideologies, or major life decisions during a period of heightened suggestibility or emotional openness.

With patient consent, family members or other trusted supports may help with transportation, first-night planning, education about warning signs, collateral information, and follow-up. Programs should avoid assuming that every patient has an available caregiver or shifting clinical responsibilities onto families without support.

Every program should establish who remains clinically responsible after administration, how urgent concerns are triaged, how existing clinicians are informed with consent, and what is available to nonresponders or people who experience deterioration or harm. A responsible system must be designed not only for responders. Programs should maintain pathways for additional visits, medication management, evidence-based psychotherapy, crisis care, higher levels of care, and independent reporting of adverse experiences.

E. Training, supervision, quality assurance, and certification

HRSA should support a national competency framework with a shared core and role-specific and product-specific requirements. The shared core should address pharmacology; evidence and uncertainty; patient selection; trauma and dissociation; suicidality; psychosis and mania; cultural humility; ethics, boundaries, touch, and suggestibility; emergency procedures; documentation; adverse-event reporting; and care for nonresponse or harm. Product-specific training should address dose, formulation, expected effects, contraindications, interactions, monitoring, discharge, and label or REMS requirements.

BrainFutures, one of our partner organizations, is currently working on development of core competencies to support training and education. HRSA should review and coordinate with ongoing national competency-development efforts rather than creating duplicative standards, while ensuring that any federal framework remains transparent, evidence-based, multidisciplinary, and independent of any single manufacturer or training organization.

Training should combine didactic education, observed skills practice, simulation, supervised practicum, case consultation, and ongoing quality review. A certificate of attendance is not evidence of competence. Competence should be demonstrated through observed performance, simulation, supervised experience, and periodic reassessment. Quality assurance should include review of serious adverse events, emergency transfers, boundary and patient-experience concerns, fidelity, retraining, and routine emergency drills. Regional simulation and supervision can help low-volume rural sites maintain competence without creating unrealistic local volume requirements.

State-regulated psilocybin programs in Oregon and Colorado may provide useful implementation lessons for HRSA. Emerging real-world safety data from these programs are observational and remain limited in follow-up, but to date have not identified clear safety signals that would support substantially more burdensome requirements solely on the basis of supervised psilocybin administration. Clinical requirements should ultimately remain tied to the FDA-approved product, label or REMS, patient population, setting, and evolving evidence.

Practitioner certification, if required, should be transparent, evidence-based, portable, and affordable. It should not rely solely on manufacturer-controlled training or create unnecessary profession-specific restrictions. HRSA should fund regional hubs, train-the-trainer programs, tele-supervision, and apprenticeship partnerships so that rural and safety-net clinicians can obtain high-quality training without costly travel or dependence on a small number of proprietary programs.

II. Restoration Through Ethical Stewardship

Because restoration reflects whether individuals are able to resume meaningful participation in family, work, education, and community life, it aligns closely with HRSA's mission to improve health outcomes in underserved communities. Psychedelic care may involve periods in which patients are emotionally open, suggestible, physically impaired, dependent on staff, or less able to advocate for themselves. Ethical protections must therefore be operational requirements rather than aspirational principles.

Informed consent should be enhanced and iterative, including written consent and an ongoing conversational process throughout preparation, when the patient is unimpaired and has time to ask questions. HRSA should adapt useful principles from research consent - including key-information-first presentation, plain language, emphasis of material risks and alternatives, and confirmation of comprehension - without importing research regulations wholesale into clinical care.

Informed consent should address expected effects; uncertainty; realistic likelihood of benefit; nonresponse and worsening; potential for acute or enduring changes in mood, self-perception, beliefs, or worldview where supported by product-specific evidence; alternatives to treatment; the role and limits of support; confidentiality; recording and data use; physical contact and touch; spiritual or cultural framing; transportation; follow-up; financial obligations; conflicts of interest; and complaint or withdrawal procedures. Consent for optional touch, recording, data sharing, or research should be especially transparent, separate, and revocable. HRSA should support baseline standardized consent resources that can be adapted to specific products, risk profiles, populations, and settings.

Programs should adopt explicit boundary policies, prohibit sexual contact and exploitation, define permissible and impermissible touch with clear and conservative boundaries (*e.g.*, hand and shoulder), address gifts and dual relationships, and use chaperone or two-person practices where indicated. Patients should have access to independent complaint mechanisms and should not be required to report concerns only through the clinic or manufacturer responsible for their care.

Ethical stewardship also requires transparency regarding commercialization. Financial incentives may favor shorter visits, fewer clinicians, proprietary certification, or product-centered models; professional interests may favor preservation of labor-intensive services. Neither should predetermine the care model. The goal should be to identify the minimum sufficient model through evidence rather than allowing reimbursement structures, commercial incentives, or professional interests to decide it in advance.

Patients should have meaningful choice where feasible, including provider gender, touch preferences, music or silence, eyeshades, inclusion of a support person, cultural or language accommodations, and the form of follow-up. Programs should provide mobility, sensory, communication, cognitive, and neurodivergence-informed accommodations and should avoid blanket exclusion based on disability.

III. Restoration Through Responsible, Evidence-Based Clinical Translation

Clinical trials evaluate specific interventions delivered under specific conditions. Evidence cannot automatically be generalized to a materially different intervention merely because the same medication is used. Contemporary psychedelic studies have generally included some combination of careful selection, preparation, prolonged clinician contact, administration-day support, and structured follow-up. These elements vary, and not all may prove necessary for every product or patient. Responsible clinical translation therefore requires attention not only to whether a medication can be administered, but also to the workforce, safeguards, infrastructure, and continuity of care needed to deliver the intervention safely and effectively in real-world settings.

Early implementation should remain reasonably aligned with the evidence-supported and FDA-approved treatment model, including components necessary for safety, ethical care, and expected effectiveness, while material adaptations are prospectively evaluated. The absence of evidence that an abbreviated model is inferior is not evidence that it is equivalent. Fidelity should not, however, become permanent rigidity; there must be flexibility within fidelity. Some early protocol elements may reflect research procedures, caution, institutional resources, or historical convention rather than clinical necessity. HRSA should support deliberate removal of requirements that evidence shows do not add sufficient value.

Existing evidence and ethical considerations support caution before substantially reducing human support. The minimum necessary type and intensity of support, however, remain empirical questions that should be evaluated across products, populations, and settings. Uncertainty should trigger structured learning, not unsupported deregulation or permanent overregulation.

Group treatment models may improve capacity, affordability, and access, but their safety, effectiveness, privacy implications, staffing needs, and suitability for different patients and products remain empirical questions. HRSA should preserve flexibility for group-based preparation, administration, or follow-up while supporting prospective evaluation of these material adaptations.

A practical implementation framework should include four layers:

1. A shared national core: informed consent, eligibility assessment, emergency readiness, boundaries, documentation, safe discharge, continuity, and adverse-event reporting.
2. Product-specific requirements: pharmacology, route, duration, physiological and psychiatric risks, interactions, monitoring, discharge, and any label or REMS elements.
3. Patient-specific requirements: illness severity, comorbidity, prior response, suicidality, trauma, cognition, substance use, social support, transportation, preferences, and access to follow-up.
4. Setting-specific requirements: workforce, room design, emergency response time, controlled-substance rules, referral capacity, broadband, accessibility, and rural or frontier constraints.

IV. Ambulatory Clinic Readiness and Operations

A. Essential and desirable clinic features

Ambulatory settings can deliver these therapies safely when they have the necessary workforce, environment, controlled-substance processes, emergency procedures, and continuity of care. HRSA should avoid assuming that only academic medical centers can meet these standards, while also avoiding certification that exists on paper without functional readiness.

Essential capabilities should include:

- Private, accessible, and uninterrupted treatment space appropriate for the anticipated duration.
- Direct observation or immediate access consistent with the product and approved model.
- Vital-sign and emergency equipment appropriate to demonstrated risk.
- Medication reconciliation and clearly assigned clinical accountability.
- Controlled-substance receipt, storage, inventory, waste, and diversion controls.
- Secure documentation, prearranged emergency response, and closed-loop referral pathways.
- Evidence-based discharge criteria, transportation planning, and reliable follow-up.
- Video monitoring and recording, whether optional or required for a specific intervention.

Desirable features may include adjustable lighting, noise control, comfortable furnishings, culturally responsive design, music where appropriate, accommodation of a support person, and calming transitional space. These features may improve the patient experience, but highly curated rooms or specialized equipment should not become costly prerequisites unless evidence demonstrates clinical value.

Patients should not drive, operate machinery, or execute legal or financial documents after discharge on the day of administration. Discharge should be based on orientation, cognition, judgment, mobility, vital signs, psychiatric stability, transportation, and a realistic plan for the first night and following day, not elapsed time alone. Rural patients may face lodging, childcare, lost wages, and multiday travel; these are meaningful access barriers.

B. Controlled substances, certification, and common operational challenges

Storage, security, and inventory requirements should follow the product's federal schedule, applicable state law, and relevant FDA requirements. New psychedelic-specific layers should not be added to existing controlled-substance systems unless they address a demonstrated gap. HRSA should coordinate

with FDA, DEA, states, and manufacturers on plain-language checklists, model standard operating procedures, accountability and waste templates, and registration guidance.

If site certification is required via REMS, HRSA should not impose duplicative certification requirements. We encourage shared foundational standards, with product-specific add-ons only as necessary for safety. Certification should be no-cost or low-cost for safety-net and community sites and should include technical assistance, implementation funding, readiness assessment, model policies, and remediation support rather than functioning only as a pass/fail barrier.

Common challenges will include capital costs and prolonged room occupancy; reduced productivity during lengthy sessions; cancellations and scheduling complexity; workforce shortages; pharmacy and controlled-substance infrastructure; emergency-transfer arrangements; training and supervision costs; reimbursement uncertainty; transportation and lodging; cross-state telehealth restrictions; broadband and IT support; limited referral capacity; and sustaining programs where treatment volume is low.

C. Workforce capacity and reimbursement

Long administration sessions will reduce room turnover and clinician productivity under conventional outpatient models. Clinics will need protected rooms, staggered scheduling, cross-coverage, defined emergency roles, post-session staffing, and contingency plans for sessions that extend beyond the expected duration. Group protocols (including preparation, administration, or integration sessions) telehealth preparation and follow-up, regional hubs, mobile support teams, and coordinated networks may improve efficiency, but should be evaluated rather than assumed equivalent.

Reimbursement should cover the full evidence-based episode of care, not only the drug or administration procedure. Existing payment methodologies for FQHCs, CCBHCs, and other safety-net settings were not designed around multi-hour administration sessions and may not reliably cover the full costs of this model. HRSA should work with CMS and payers to evaluate bundled, adjusted, or other payment approaches that account for screening, medical evaluation, preparation, administration-day monitoring and support, facility costs, product acquisition and storage, care coordination, follow-up, management of complications, and quality reporting. Within its own authority, HRSA should ensure that health-center funding, sliding-fee requirements, technical assistance, and implementation supports account for the additional operational burden on safety-net settings and uninsured or underinsured patients.

Benefit design should not leave open whether these services fall under medical or behavioral health benefits, should not cover a narrower population than the FDA approves, and should not push patients into hospital settings when the label supports ambulatory care. Administrative requirements also need to account for what serious mental health conditions do to a patient's capacity to manage paperwork and deadlines. Patients lose coverage over missed forms during the very episodes that make forms hardest to complete. HRSA should work with CMS and payers to reduce prior-authorization and documentation burdens that serve no safety purpose, and to support transportation, lodging, childcare, and caregiver costs where those are what stand between a patient and finishing treatment.

The value of these investments extends beyond the service itself. The workforce, referral and emergency pathways, quality systems, and physical infrastructure required here would also support other evidence-based behavioral health care, including emerging device-based treatments such as accelerated TMS. Without sustainable payment and implementation support, health centers may be unable to offer these therapies at all, and patients who are least able to travel or pay out of pocket will be most likely to go without potentially lifesaving and life-restoring care.

V. Technology in Service of Humanity

AI, digital health, on-site video capabilities, telehealth, remote monitoring, and simulation may expand capacity, but they should be governed by clinical purpose, evidence, human accountability, privacy, accessibility, and equity.

A. Highest-value near-term uses

The strongest near-term opportunities include asynchronous education and preparation support; structured history collection and clinician decision support; on-site video monitoring and recording, telehealth follow-up and case consultation; measurement-based care and between-visit safety monitoring; documentation and workflow support; simulation-based training; and regional tele-supervision and multidisciplinary review. The most uncertain and highest-risk application is replacing in-person human observation during acute administration.

B. Screening and eligibility

Digital and AI-based tools can collect histories, reconcile medications, score validated measures, identify possible contraindications, organize records, and prompt clinicians to address missing information. They should not make final eligibility decisions. A qualified clinician should review outputs, resolve discrepancies, document uncertainty, and remain accountable.

C. Monitoring during administration

On-site video monitoring and, where appropriate, recording may provide an important additional safeguard for patient safety, professional accountability, quality assurance, and independent review. This may be particularly relevant during prolonged sessions, when touch is authorized, or when a complaint or serious adverse event requires retrospective review. Recording can provide an objective contemporaneous record, but it also raises meaningful questions about privacy, autonomy, trust, data security, and patient choice; those tradeoffs should be addressed explicitly rather than treated as incidental.

Video capabilities may also have implications for access and staffing. Because prolonged, resource-intensive sessions may be especially difficult for rural, Tribal, and safety-net sites, video monitoring could support risk-stratified models of care if prospective evidence demonstrates that it can do so without reducing safety, trust, or quality. It should not be assumed to justify lower staffing in advance of such evidence.

HRSA should consider video capability as one component of a broader safety and scalability architecture, while distinguishing the ability to record from a requirement that every patient be recorded. Where video or recording is required by a product label, REMS, institutional policy, or other applicable standard, implementation funding should include equipment, secure storage, information security, and governance needed to protect these records.

Where recording is not required, patients should generally be able to decline. When enhanced observation safeguards are clinically or institutionally indicated, reasonable alternatives may include a second staff member, an agreed-upon support person when appropriate, or structured check-ins by another trained staff member. Programs should define these options in advance without assuming that every patient has an available support person.

Informed consent should specify who may view the recording, for what purposes, how long it will be retained, when it will be destroyed, and how the patient may obtain a copy of their own session. Recordings are protected health records that must comply with applicable federal and state law – they should be stored encrypted, with logged and role-limited access; used only for clinical care, quality assurance, adverse-event and complaint review, and patient request; and destroyed on a defined schedule. The use of recordings for supervision and training may be permitted with separate consent.

The use of physiological sensors, video analytics, acoustic tools, and alerts may provide an additional safety layer, but should not initially substitute for on-site human presence during acute experience or impairment. Current systems have not demonstrated reliable capacity to interpret relational, cultural, trauma-related, coercive, or boundary-safety concerns with the contextual judgment required for independent clinical care. Automated monitoring should have validated performance, clear thresholds,

human review, fail-safe procedures, cybersecurity protections, and a trained person able to intervene immediately.

HRSA should support prospective studies before technology is used to reduce required human staffing. These studies should examine medical events, distress, trust, adverse psychological experiences, privacy, false alarms, missed events, clinician workload, and performance across racial, cultural, disability, age, and language groups.

D. Follow-up, training, accessibility, and quality improvement

Conversational or integration tools may help people organize questions and track goals, but should not present themselves as therapists, offer authoritative interpretations, or manage crises without immediate human escalation. Programs should accommodate low bandwidth, disabilities, language needs, limited digital literacy, shared devices, privacy constraints, and limited local IT support. HRSA grants and technical assistance should include the infrastructure required to use mandated technologies; otherwise, digital requirements will become unfunded barriers.

VI. Restoration Through Equitable Access

Equity should be built into implementation from the beginning. Rural communities, Tribal Nations, Veterans, people with disabilities, caregivers, low-income patients, racial and ethnic minority communities, and people with complex comorbidities often face overlapping barriers involving distance, workforce, broadband, trust, transportation, cost, language, and continuity.

HRSA should invest in regional centers of excellence that support, rather than replace, community delivery. Hubs can provide consultation, tele-supervision, training, pharmacy, infrastructure, and regulatory assistance, quality improvement, and referral pathways, while spoke sites provide care closer to home. Mobile teams and temporary regional clinics may help low-volume areas when they preserve continuity, emergency readiness, and follow-up. These investments should strengthen local capability over time rather than create permanent dependence on distant specialty centers.

Requirements that appear neutral may produce unequal access. Certification fees, proprietary training, excessive room specifications, inflexible staffing ratios, unpaid follow-up, distant hospital travel, and broadband-dependent platforms may concentrate care in affluent urban centers. Every proposed requirement should be evaluated for demonstrated safety value, implementation burden, and disparate impact. Resource-constrained settings should not be asked to deliver a less-supported or lower-quality model merely because resources are limited; they should receive the investment needed to provide high-quality care and participate in the research that determines safe adaptation.

Indigenous communities should not be treated as a monolithic endorsement of psychedelic use. Meaningful participation should include authority, reciprocity, benefit sharing, protection of knowledge, and support for Indigenous-led research and care models. Similar shared-governance principles should include patients, Veterans, caregivers, community clinicians, disability advocates, rural and safety-net leaders, and informed skeptics.

VII. Measuring Restoration and Building a Learning Health System

HRSA should help establish a learning health system that detects safety problems, evaluates real-world effectiveness with a focus on restoration and well-being, compares delivery models, and identifies inequities. Measurement should be feasible enough for community settings and meaningful enough to guide care, policy, and continuous improvement.

Safety reporting should distinguish expected pharmacodynamic effects from clinically adverse events while capturing both. Programs should record intensity, duration, participant appraisal, distress, impairment, intervention required, persistence, and resolution. Difficult experiences should neither be automatically pathologized nor romanticized. Safety systems should also capture patient-reported and nontraditional harms, including prolonged psychological distress, functional deterioration, boundary

violations, coercive experiences, or clinically meaningful relational or behavioral consequences. Patients should have an avenue to report safety concerns independently of the treating program or manufacturer.

HRSA should work with FDA, CMS, SAMHSA, VA, NIH, and other partners on a minimum common data set and an interoperable registry or distributed data network. There should be a focus on capturing unique adverse events and on measuring well-being and restoration beyond symptom scores, using a consensus validated instrument such as WHO-5, WEMWBS, the Mental Health Continuum–Short Form, and the Flourishing Scale, alongside functional measures such as WSAS and WHODAS 2.0.

Participation should protect privacy, avoid excessive burden, permit independent analysis, and include patient and community governance. Small clinics should not be excluded from learning-system participation simply because they lack resources; implementation funding should support the staff, technology, and technical assistance necessary to contribute.

Priority implementation studies should compare preparation intensity, staffing ratios, support models, telehealth, remote monitoring, follow-up schedules, group-based components, training pathways, and accessibility adaptations. Studies should determine which components are essential, which benefit particular patients, which can be delivered flexibly, and which add burden without sufficient value.

Domain	**Examples**
Clinical	Symptoms, suicidality, substance use, sleep, adverse events, medication changes, relapse, retreatment, and durability.
Functional	Work or education, parenting, daily activities, cognition, housing stability, relationships, and healthcare engagement.
Restoration	Purpose, hope, identity, autonomy, belonging, meaning, quality of life, patient-defined goals, and a life experienced as worth living.
System	Access, wait time, completion, workforce burden, clinic capacity, cost, utilization, rural reach, disparities, and sustainability.

VIII. Priority Actions for HRSA

- Adopt restoration and well-being as guiding objectives and encourage outcomes extending beyond symptom reduction to functioning, relationships, purpose, quality of life, sustained recovery, and patient-defined benefit and harm.
- Develop a national competency framework with shared, product-specific, role-specific, and setting-specific requirements.
- Fund regional training, supervision, simulation, and technical-assistance hubs for FQHCs, CCBHCs, Rural Health Clinics, Tribal health systems, VA-connected community partners, and other underserved settings, and technology implementation costs such as video monitoring, recording, and IT costs.
- Create model protocols and readiness tools covering screening, consent, role allocation, collaboration, boundaries, emergencies, discharge, controlled substances, adverse events, continuity, accessibility, independent complaint and safety reporting, recording safeguards where applicable, and care for nonresponse or harm.
- Preserve reasonable alignment with the evidence-supported and FDA-approved treatment model during early implementation while funding comparative studies of material adaptations.
- Treat AI, digital tools and monitoring technologies as accountable clinical adjuncts, with human oversight, validation, privacy and cybersecurity protections, accessibility, patient choice where feasible, and equity review.
- Align certification and facility requirements with demonstrated risk and provide no-cost or subsidized pathways for safety-net and rural sites.
- Coordinate with CMS and payers on reimbursement that covers the full evidence-based care pathway and avoids benefit-category confusion or restrictions narrower than the FDA label.
- Build a learning health system with common safety, clinical, functional, restoration, equity, and system outcomes, and establish an independent patient-initiated reporting pathway for adverse events and safety concerns that does not run through the treating clinic, certifying body, or manufacturer.
- Include patients, Veterans, caregivers, community clinicians, skeptics, disability advocates, rural leaders, and Indigenous communities in governance and implementation decisions.

Conclusion: Preparing Healthcare Systems, Not Only Clinicians

Psychedelic medicines are not the destination. They are one potential catalyst for a broader transformation in behavioral healthcare. The decisions made now will determine whether emerging treatments become isolated specialty services available primarily to affluent patients near academic centers, or help create durable infrastructure for high-quality care across community, rural, Tribal, public-sector, and Veteran-serving systems.

The task is not to choose between rigor and compassion, safety and access, human care and technology, or fidelity and innovation. It is to build systems capable of holding these priorities together. Standards should be rigorous enough to protect patients, proportionate enough to remain feasible, flexible enough to evolve with evidence, and humane enough to recognize what treatment asks of people living with serious illness.

A person living with severe PTSD, depression, suicidality, addiction, or moral injury does not simply need a drug administered under observation. They need to know that if something painful, destabilizing, or profoundly important is opened, someone competent will still be there afterward.

The measure of a behavioral health system is not simply how well it reduces symptoms, but how well it restores lives.

Sincerely,

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Appendix A. Direct Responses to HRSA's Questions

RFI question	RFH/VMHLC recommendation	Section
Separate screening from diagnostic assessment?	Generally yes. Use a standardized initial screen followed by a comprehensive clinician-led evaluation with clear escalation rules.	**I.A**
Who may conduct screening and evaluation?	Trained staff may perform initial screening. Licensed professionals should complete diagnosis, medical clearance, prescribing, psychotherapy, and other functions requiring licensure or legal authority.	**I.A-I.B**
Is a new state psychedelic-provider license required?	Not presumptively. Use existing licensure, scope of practice, competency verification, and site credentialing unless a defined regulatory gap remains.	**I.B**
May telehealth be used before treatment?	Yes for preliminary screening, education, collateral interviews, some preparation, and case review. In-person examination should be used when required by the label, law, or clinical need.	**I.A**
How should multiple providers collaborate?	Use a named coordinating clinician, shared plan, consent-based information exchange, closed-loop referrals, written handoffs, and explicit responsibility for delayed concerns.	**I.B**
What training is needed?	Didactics, observed skills practice, simulation, supervised practicum, consultation, quality review, and periodic competency reassessment.	**I.E**
Can peers participate?	Yes. Peers should contribute to navigation, education, engagement, therapeutic and recovery support, and community connection, but not as substitutes for licensed functions outside their scope.	**I.B**
What staffing is needed during administration?	Risk-stratified staffing with immediately available human assistance and medical response capability appropriate to the product, patient, and setting.	**I.C**
What are essential ambulatory clinic capabilities?	Accessible private space, monitoring and emergency readiness, video monitoring and recording capabilities, controlled-substance systems, secure documentation, discharge and transportation planning, and reliable follow-up.	**IV.A**
What features are desirable but not automatically required?	Adjustable lighting, noise control, comfortable furnishings, culturally responsive design, music, support-person accommodation, and calming transitional space.	**IV.A**

RFI question	RFH/VMHLC recommendation	Section
Which technologies have greatest near-term value?	Education, structured history collection, decision support, on-site video monitoring and recording administration sessions, telehealth follow-up, measurement-based care, documentation, simulation, and tele-supervision.	**V.A**
Can technology replace human observation?	Not initially. Any reduction in on-site human staffing should follow prospective evidence demonstrating safety, quality, trust, and equity.	**V.C**
How should HRSA support underserved settings?	Fund regional hubs, technical assistance, subsidized certification, infrastructure, transportation and lodging support, and community-based research participation.	**VI**
How should outcomes be measured?	Use clinical, functional, restoration, and system outcomes, including safety, durability, equity, access, and patient-defined benefit and harm.	**VII**
Should a licensed medical provider evaluate the patient before administration, and be available on site during the session?	Yes to pre-administration medical evaluation. A medical clinician competent to respond to foreseeable complications should be immediately available on site, or through a clearly defined alternative providing equivalent response capability, consistent with the product risk profile, label, and local emergency capacity.	**I.C / IV.A**
Should administration sessions be recorded?	Sites should have appropriate video capability when required or justified by the treatment model. Video monitoring or recording may support patient safety, clinician accountability, independent review, and - if supported by prospective evidence - risk-stratified staffing. Where recording is not required, patients should generally be able to decline, with alternative safeguards available when enhanced observation is otherwise indicated.	**V.C**
How should informed consent be obtained?	Enhanced and iterative: written consent using key-information-first, plain-language principles adapted from research consent, plus an ongoing conversational process throughout preparation while the patient is unimpaired. Consent for optional touch, recording, data sharing, and research should be transparent, separate, and revocable.	**II**
May psychedelic therapies be administered in group settings?	Group-based models may improve capacity and access but should be prospectively evaluated for safety, effectiveness, privacy, staffing, and patient suitability. HRSA should preserve flexibility for evidence-based adaptation as data develop.	**III / IV.C**

RFI question	RFH/VMHLC recommendation	Section
Should requirements differ for different formulations?	Yes. Psychedelic products are not a single operational category. Administration and observation requirements should follow the product label and REMS, informed by pharmacology, dose, route, duration, intensity of subjective effects, medical and psychiatric risk, and approved indication, over a shared minimum core.	**I.C / III**
Should health centers be required to achieve certification?	Where certification is required via REMS, HRSA should not impose duplicative requirements. We encourage shared foundational standards with product-specific add-ons only as necessary for safety, provided at no or low cost to safety-net and community sites with technical assistance and implementation funding.	**IV.B**
What facility, storage, security, and inventory-control requirements are needed?	Requirements should follow the product's federal schedule, applicable state law, and relevant FDA requirements. New psychedelic-specific layers should not be added to existing controlled-substance systems absent a demonstrated gap. HRSA should provide plain-language checklists, model SOPs, and registration guidance.	**IV.B**
How long should patients be observed, and when may they be discharged?	Discharge should be based on orientation, cognition, judgment, mobility, vital signs, psychiatric stability, transportation, and a realistic plan for the first night and following day, not elapsed time alone. Patients should not drive or execute legal or financial documents that day.	**IV.A**
How will the care model affect workforce productivity and clinic capacity?	Long sessions reduce room turnover and clinician productivity. Clinics will need protected rooms, staggered scheduling, cross-coverage, defined emergency roles, and post-session staffing. Group protocols, telehealth preparation and follow-up, regional hubs, and coordinated networks may improve efficiency but should be evaluated rather than assumed equivalent.	**IV.C**
How should these services be reimbursed?	Payment should cover the full evidence-based episode, not only the drug or administration procedure, and should address per-encounter FQHC and CCBHC payment rates that cannot cover a multi-hour session. Benefit design should avoid medical-versus-behavioral ambiguity, restrictions narrower than the FDA label, and hospital-only requirements.	**IV.C**

RFI question	RFH/VMHLC recommendation	Section
How should adverse events be captured and reported?	Distinguish expected pharmacodynamic effects from clinically adverse events while capturing both, recording intensity, duration, appraisal, distress, impairment, intervention, persistence, and resolution. Patients should always be able to report safety concerns independent of the program or manufacturer.	**VII**

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