PUBLIC COMMENT

Considerations for Potential Future Therapeutic Use of Psychedelic Drugs

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Submitted by	Center for Psychedelic Public Health and Zendo Project
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Primary contact	Missi Wooldridge MPH Co-Founder, Center for Psychedelic Public Health (CPPH) missi@psychedelicpublichealth.org
Authorized signatory/signatories	Chelsea Rose Blake Pires M.A., LMFT, Zendo Project Veena Muthusamy-Flok MBA, Zendo Project Heather Kuiper DrPH, MPH, CPPH
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Introduction and Qualifications

The Center for Psychedelic Public Health (CPPH) and Zendo Project appreciate the opportunity to comment on the potential future therapeutic use of psychedelic drug products in supervised and supportive settings. CPPH contributes expertise in public health practice, implementation science, health equity, workforce evaluation, substance use education, and community-based harm reduction. Zendo Project contributes practice-based expertise in compassionate psychedelic peer support and education for people who may encounter or support individuals experiencing altered states.

Zendo Project has provided psychedelic peer support services since 2012, supporting more than 7,500 guests and training more than 10,000 people. Its education spans several settings and audiences. Zendo has trained volunteers and staff providing psychedelic peer support at festivals and other events since 2012. In 2024, Zendo launched its publicly available Sitting and Integration Training (SIT), which has trained more than 2,000 people in psychedelic harm reduction and peer support and offers 12 continuing education (CE) credits through Spiritual Competency Academy. In 2025, Zendo expanded its training for professional crisis responders, including community crisis response teams and emergency department personnel. Across these programs, Zendo has trained peer supporters, clinicians, emergency medical personnel, crisis workers, event staff, security personnel, and community members.

Together, CPPH and Zendo Project offer a public health and harm reduction perspective on how community-informed knowledge can strengthen safety, workforce capacity, and equitable implementation in regulated therapeutic settings. We do not suggest that peer support is psychotherapy, that community experience substitutes for clinical evidence, or that non-clinical personnel should act beyond scope. We recommend clearly bounded, competency-based roles within an accountable continuum of care.

Scope of This Comment

This joint comment responds primarily to FDA's questions concerning (1) provider training and credentialing, (2) promotion of patient safety, and (3) considerations for access. We address selected data needs. We do not address the safety or effectiveness of any particular product or pending application, substance scheduling, legalization or decriminalization, religious or personal use, or individual disputes.

Our recommendations concern potential future therapeutic use in supervised and supportive settings. Examples from community-based practice are included to offer transferable operational lessons, such as compassionate communication, environmental de-escalation, role clarity, recognition of warning signs, and timely escalation, not as evidence that unregulated and regulated settings are equivalent.

Summary of Recommendations

Recommendation 1: Convene a multidisciplinary standards process.

Include compensated clinical, emergency, public health, harm reduction, peer, patient/client, equity, disability, and Indigenous expertise.

Recommendation 2: Adopt a tiered, function-based workforce framework.

Define competencies, permissible functions, supervision, escalation, and referral requirements by phase of care and level of risk; assign correspondingly trained professionals. Specify permitted functions, assessment, supervision, practice requirements, referral thresholds, continuing education, and renewal.

Recommendation 3: Use competency-based, experiential training.

Combine foundational instruction with demonstration, scenario-based practice, coached roleplay, observed assessment, supervised experience, continuing education, and communities of practice.

Recommendation 4: Recognize bounded non-prescriber and peer roles.

Integrate appropriately trained community health workers, public health nurses, health educators, social workers, and peers into comprehensive service models.

Recommendation 5: Treat safety as a continuous pathway, with connected safety protocols

Connect screening, preparation, set and setting, ongoing consent, administration, emergency escalation, discharge, integration, follow-up, accountable handoffs, and complaints through written protocols.

Recommendation 6: Build equity into implementation and payment.

Evaluate who can enter, afford, trust, complete, and benefit from care; reimburse essential non-drug services; and partner with trusted community-based hub-and-spoke and safety net organizations.

Recommendation 7: Develop balanced patient and public education.

Use accessible, culturally responsive, non-promotional materials explaining potential risks, benefits, protective factors, credentials, consent rights, complaint pathways, and when to seek urgent help.

Recommendation 8: Evaluate workforce, safety, and access.

Use common measures that distinguish training outcomes, observed competency, patient outcomes, ethical concerns, and implementation effects.

Provider Training and Credentialing

Standards Development Body

FDA and federal partners should convene a multidisciplinary and compensated standards process that includes expertise in mental health, primary care, emergency medicine, public health, nursing, pharmacy, implementation science, health education, provider training, harm reduction, peer support, disability access, health equity, patient/client experience, ethics, and relevant state and tribal systems. Indigenous leadership should have decision-making authority when standards draw upon Indigenous medicines, practices, knowledge, or intellectual property. No single profession should control competencies that span settings and functions.

Personnel by Phase of Care

Phase	Core functions	Potential contributors	Boundary and escalation requirements
Screening and preparation	Medical and psychiatric risk assessment; medication and substance review; education; consent; logistics; support planning.	Qualified prescribers and clinicians, nurses, pharmacists, care coordinators, health educators, trained peers or navigators.	Diagnosis, eligibility decisions, prescribing, and clinical risk determination remain with authorized clinicians. Peers and navigators identify concerns and refer rather than diagnose.
Dosing, administration, and monitoring	Protocol-driven dosing; Continuous observation; supportive presence; documentation; recognition of distress or medical change; emergency activation.	Any personnel meeting established requirements, with additional trained support roles as permitted.	Written protocol, immediate access to clinical decision-makers, continuous coverage, and no clinical action by personnel outside scope.
Discharge and transition	Readiness assessment; transportation and support plan; written safety information; warm handoff.	Clinical provider for assessment; any personnel meeting established requirements for other functions,	Clinical personnel determine discharge readiness; others reinforce the plan and activate escalation when needed.
Follow-up and integration	Symptom and safety checks; integration support; navigation; referral; continuity with primary and behavioral health care.	Treating clinicians, behavioral health, social workers, community health workers, peer-support specialists.	Role-specific documentation, supervision, referral thresholds, and rapid clinical reassessment for warning signs.

Non-Prescriber and Peer Roles

Non-prescriber personnel can contribute relational continuity, plain language education, navigation, observation, grounding, reflective listening, connection to social resources, and warm referral. Peer support may add trust and experiential understanding, but it should not be equated with psychotherapy or medical management. Published scholarship identifies a potential role for trained psychedelic peer support while emphasizing needs for competencies, supervision, and ethical clarity (Skiles et al., 2023). SAMHSA likewise recognizes peer specialists and community health workers as contributors to engagement, navigation, social needs response, and continuity within community behavioral health systems (SAMHSA, 2024).

Foundational competencies should include role clarity; nonjudgmental and person-centered communication; trauma- and culturally responsive practice; consent and boundaries; self-regulation; grounding and de-escalation; recognition of medical and psychiatric warning signs; documentation; referral; and emergency activation. Advanced competencies should correspond to defined functions, settings, and risks.

Competency Assessment and Maintenance

Training should be theory-informed, competency-based, and evaluated for transfer to practice. The CPPH evaluation of Zendo SIT used a public health and workforce behavior change framework addressing delivery, knowledge and skills, motivation, self-efficacy, readiness, transfer context, application, and longer-term outcomes. Preliminary findings suggest that experiential learning, including scenarios, demonstration, coached roleplay, reflective practice, and peer-to-peer learning, is important and relevant even when trainees possess varied professional backgrounds.

Credentialing should assess demonstrated performance rather than relying only on attendance or self-reported confidence. Possible methods include knowledge checks, observed structured scenarios, feedback, supervised practice, and periodic renewal. One-time certification should be supplemented by continuing education and consultation or supervision. Credentialing frameworks should recognize existing professional, peer support, community health worker, and emergency response structures where feasible rather than creating parallel systems.

Minimum Staffing During Administration

Two providers during a session is optimal, including at least one female when the client/patient is female. However, while these providers need to be trained in facilitation skills, they do not need to be clinicians, especially if a medical consult is onsite. Peer or support personnel may supplement, but should not replace, required qualified monitors absent evidence and an appropriate regulatory determination.

Promotion of Patient Safety

Screening and Risk Stratification

Screening should support risk stratification, informed planning, appropriate placement, and referral. Qualified clinicians should assess relevant cardiovascular and neurologic conditions; psychosis, mania, suicidality, and other psychiatric risks; pregnancy when relevant; medications and supplements; recent substance use and interaction risks; prior responses to altered states; trauma and interpersonal safety; cognitive and communication needs; practical support; transportation; and the safety of the recovery environment. Protocols should specify when to defer treatment, request additional consultation, modify the care plan, or use a setting with greater medical capability. Non-clinical personnel may collect standardized information and identify red flags but should not make clinical eligibility decisions.

Set, Setting, and Education

Set and setting should be addressed as modifiable safety factors. Programs should consider sensory load, privacy, physical comfort, accessibility, cultural meaning, patient preferences, and the involvement of a trusted support person when clinically and operationally appropriate. Zendo’s practice-based observation is that a calm, compassionate, nonjudgmental supporter and a low-stimulation environment may help reduce distress and avoidable escalation, albeit this observation is not a clinical effectiveness claim. For example, in qualitative interviews that Zendo Project conducted with former clients in 2023, one attendee reported seeking the Zendo space because she could sit or lie down with her eyes closed, away from foot traffic, and know she would not be disturbed, while also having someone available to talk with about her experience. She described that combination of a quieter, protected setting and a calm, available person as "really the best thing." This account is self-reported and retrospective and is offered as an illustration of practice, not as evidence of effectiveness.

Patient education should explain the expected course and uncertainty of the experience; possible physical, psychological, relational, and functional effects; medication and substance interaction considerations; the difference between expected acute effects, a challenging experience, and an emergency; available supports; and how concerns will be documented and reported. Materials should be plain language, accessible, multilingual where needed, culturally responsive, and non-directive and balanced rather than promotional or fear-based.

Informed Consent and Accountability

Informed consent should be an ongoing process rather than a single form. Before administration, patients should receive clear information and provide written consent about dosing, power differentials and suggestibility; staff roles; confidentiality and its limits; documentation, recording, or observation; touch and non-touch options; withdrawal of consent; emergency procedures; independent complaint pathways. Consent for touch should be specific and documented in advance. A patient may narrow or withdraw consent during a session, but a request made under acute drug effects should not expand previously

established boundaries, especially concerning touch and dose. Research supports advance, specific, and continuing consent for touch and explicit boundary management procedures (McHerron et al., 2025).

Programs should maintain enforceable codes of conduct, supervision, documentation, independent and accessible complaint mechanisms, non-retaliation protections, transparent investigation procedures, and referral to licensing, employment, law-enforcement, or other authorities when applicable. Clients/patients need a reporting route outside the immediate provider relationship because the therapeutic power imbalance may impede disclosure.

Crisis Response and Follow-Up

Facilities should maintain written pathways for early distress, behavioral escalation, suicidality, psychosis or mania, cardiovascular events, and other medical emergencies. Agreements with emergency medical services, crisis teams, emergency departments, and receiving clinicians should address communication, transport, handoff, and post-event review. Personnel likely to encounter patients after discharge, including EMS, emergency clinicians, crisis workers, and public safety teams, need role-appropriate education in compassionate, non-stigmatizing responses to altered states.

Follow-up should be a planned pathway rather than one or two isolated contacts. Each patient should receive an accessible plan identifying expected aftereffects, warning signs, after-hours contacts, crisis options, medication and substance guidance, and scheduled follow-up. Stepped support may include routine clinical checks, integration, ongoing peer or group support, and rapid reassessment for persistent functional impairment, suicidality, mania, psychosis, or other concerning changes. Peer support specialists or trained individuals may listen, normalize, navigate, and connect; clinicians retain responsibility for diagnosis and treatment.

Diversion and Non-Medical Use

From a public health and harm reduction perspective, controls should be proportionate, evidence-informed, and evaluated for unintended effects on access, stigma, emergency help-seeking, and patient trust. Appropriate measures may include secure chain of custody, inventory reconciliation, authorized handling, documentation, staff training, patient education about storage and non-sharing, and non-punitive reporting of losses or near misses. Federal partners should distinguish product security from patient education and should test whether controls create safety-net or access barriers for rural, disabled, or otherwise underserved patients.

Considerations for Access

Equity and Community Infrastructure

An access strategy should examine who can enter, afford, trust, complete, and benefit from care and who bears the burdens of restrictive requirements. Reviews continue to document ethnoracial underrepresentation and limited socioeconomic reporting in psychedelic trials (Grossman et al., 2025; Hughes & Garcia-Romeu, 2024). Federal partners should evaluate eligibility rules, referral pathways, time and travel, disability and language and cultural access, digital access, insurance design, out-of-pocket costs, retention, and patient experience, with stratified analysis where sample size and privacy permit.

Community health centers, federally qualified health centers, rural and tribal health systems, safety net hospitals, community behavioral health organizations, harm reduction and drug user health programs, syringe services programs, and organizations serving people experiencing homelessness may contribute trusted education, referral, navigation, follow-up, and social support. Not every site must administer a psychedelic product. Hub-and-spoke models can reserve administration for appropriately equipped sites while distributing selected education, navigation, coordination, and follow-up through trusted partners with defined scopes, reimbursement, data sharing protections, and warm handoffs.

Community participation should be compensated. Patients, people with lived experience, and communities historically excluded from research or harmed by drug policy should help shape training, education, implementation, and evaluation. Where therapeutic systems draw upon Indigenous medicines, knowledge,

or traditions, Indigenous peoples and knowledge holders should have compensated and meaningful decision-making roles. This recommendation concerns ethical therapeutic implementation.

Telehealth

From a public health perspective, telehealth may improve access to education, selected screening activities, care coordination, and some follow-up or integration, but it is not universally appropriate for session administration, and not all psychedelic substances are candidates for telehealth. Protocols should assess clinical risk, privacy, the patient's physical location, emergency contacts and local response capacity, communication needs, digital literacy, device and broadband access. Programs should offer non-digital alternatives and avoid shifting technology costs or privacy risks onto patients. Telehealth should not substitute for in-person examination or monitoring when the product, phase of care, patient risk, or applicable standard requires physical presence.

Payment and Capacity

Payment models should account for the entire care pathway; preparation, monitoring, transportation planning, interpretation and disability accommodations, navigation, peer support, care coordination, follow-up, integration, crisis response, and data collection all require resources. Economic analyses should examine costs shifted to patients, caregivers, community organizations, emergency systems, and safety net providers and should assess whether reimbursement supports participation by trusted community partners. While psychedelic care can be considered expensive, it should be considered relative to the long-term treatment and social costs of mental health and substance use conditions.

Selected Data Needs

Implementation and quality improvement systems should capture workforce role and qualifications; staffing configuration; training completion and observed competency; supervision; setting; referrals and handoffs; patient experience; complaints and ethical concerns; emergency activation; loss to follow-up; and access outcomes. Analyses should distinguish practice-based observations, self-reported outcomes, observed performance, clinical outcomes, and safety events.

Conclusion

Safe and equitable therapeutic implementation requires a prepared ecosystem with clear roles, competent and compassionate personnel, environmental and relational safeguards, accountable crisis and complaint pathways, sustained follow-up, accessible education, and trusted community connections.

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