August 13, 2026

Ann M. Sheehy, Principal Deputy Administrator
Health Resources and Services Administration
Department of Health and Human Services
5600 Fishers Lane
Room 13N194
Rockville, Maryland 20857

Submitted electronically via: http://www.regulations.gov

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

Dear Administrator Sheehy:

NASW appreciates the opportunity to submit comments on the Training and Care Delivery Models for Safe Administration of Potential FDA- Approved Psychedelic Therapies in Ambulatory Clinical Settings.

I am writing to you on behalf of the 100,000 members of the National Association of Social Workers (NASW). NASW is the largest and oldest professional social work organization in the United States. Clinical social workers (CSWS) are the largest provider of mental, behavioral and social care services in the nation and serve a crucial role in connecting individuals and families to health care services. Clinical social workers are integral to psychedelic-assisted therapy because they already provide essential preparation, integration, trauma treatment, case management, and care coordination services. Clinical social workers' expertise in coordinating care and fostering collaboration among providers is indispensable to ensuring that psychedelic-assisted therapy is delivered safely, effectively, and comprehensively.

Our comments to the request for information are as follows:

Workforce Training
The use of psychedelics with mental health treatment is complicated. It requires a culturally sensitive, pragmatic approach that considers the whole person and their environment. It includes procedures and processes well before the administration of medication that require prior screenings and assessments for appropriateness and much needed support during and following the administration of medication. As a result, the quality and standards of workforce training are not only vital but mandatory for providing appropriate treatment. Additionally, there should be publicly funded, equitable training pipelines that include community-based providers. This should avoid the creation of a two-tier workforce elite, credentialed clinicians versus under-resource frontline clinical social workers managing

downstream impacts. Training should follow a consistent framework and common guidelines across providers to build a knowledgeable, sustainable workforce and ensure equitable access to care.

The current training model consists of private and often unregulated training programs which has caused clinical social workers to pursue expensive credentials with unclear recognition and practice risks. As a result, federally recognized training standards should be embedded in accredited programs and integrated into continuing education frameworks. The federally recognized training standards should be embedded in accredited social work programs. Federal curriculum guidance will be essential in establishing required training for clinical social workers.

Pre-administration patient eligibility, screening and counseling:

Clinical social workers increasingly appear in research protocols as therapists responsible for preparation and integration which are distinct from prescribing roles. Clinical social workers should have received their Master of Social Work degree from an accredited social work program and state required supervised clinical hours.

Before providing services, clinical social workers should receive training in the risks and adverse effects of psychedelic substances; expected treatment outcomes; contraindications involving other substances or psychotropic medications; potential patient experiences; emergency management of adverse reactions; informed consent, including consent to touch; patient support throughout the therapeutic process; trauma-informed care; and ethical considerations. Furthermore, there should be mastery of medical terminology to appropriately discuss care plans with patients. Clinical social workers also should have a working knowledge of indigenous, (neo-)shamanic, counter-cultural, hedonistic and other perspectives on psychedelics to interpret patients' meaning-making, identify therapeutic benefits and potential risks, and collaborate ethically with cultural knowledge holders.

Clinical social workers are trained to perform biopsychosocial assessments which should be one of the comprehensive assessments conducted to determine appropriateness for treatment to include family and other supports when possible. A separate screening should be conducted by a medical practitioner to include a medical and psychological evaluation. Patients should also receive comprehensive information regarding the risks and potential adverse effects of the psychedelic substance, as well as the experiences that may occur following administration of the psychedelic substance.

The use of telehealth should be based on the clinical judgment of the interdisciplinary team involved in the referral, screening, and assessment process. Telehealth should consider the current laws and state regulations. As the treatment model becomes available on a larger scale it is worth considering telehealth, especially for rural areas, however, the current workforce may not be at scale to provide adequate and quality support.

With patient consent, providers should be utilizing all aspects of communication to plan for psychedelic therapies. When services are being provided in a facility that does not require patient transfer, electronic health records can be utilized to obtain pertinent information, however the referral should also be accompanied by a discussion to determine appropriateness of treatment. Documentation should include a protocol checklist, to be shared

with all providers. The interdisciplinary team should have regular structured meetings before and after sessions with all providers who plan to be involved in treatment.

When patients transition between settings, providers should coordinate safety protocols, crisis response plans, and post-administration integration strategies. Additionally, any relevant paperwork such as consent forms, biopsychosocial, medical labs, medications and collateral information should be shared with the receiving provider.

In-clinic day of drug administration:

Administration should be provided in a controlled therapeutic setting under medical supervision. Although clinical social workers are not legally authorized to prescribe or administer medication, they often collaborate with medical practitioners to help provide comprehensive care. As with screening and counseling clinical social workers should have received their Master of Social Work degree from an accredited social work program and state required supervised clinical hours.

Clinical social workers must convey the current evidence accurately, acknowledge its limits, and correct treatment-relevant misconceptions. [1]

Because clinical social workers are often listed as core clinical staff in psychedelic research protocols, specifically for psychotherapy, preparation and integration it is important for social work state licensing requirements to include explicit inclusion of psychedelic preparation and integration within clinical social work scope of practice which is distinct from prescribing authority. Clinical social workers may assume high-liability roles without clear scope of work practice recognition or license protection.

Additionally, training should be integrated into continuing education frameworks that are in alignment with existing social work competencies such as trauma, SUD and ethics. Clinical social workers should be knowledgeable of risks, symptoms, potential experience and emergency response protocols for in-clinic day of training administration.

Because patients may have a physical and/or psychological encounter which may lead to a vulnerable state of expansion after receiving the substance telehealth and/or remote monitoring may not be an acceptable means of care for patients during administration and observation. Medical practitioners should be available to assess vitals and emergency readiness during and after the dosing session.

Post administration follow-up:

In all, existing data and experience indicate that the preparation for psychedelic administration (i.e., set), support during administration (i.e., setting), and therapeutic follow-up (i.e., integration) are extremely important to avoid adverse events and increase the

[1] Max Wolff, Hans Rutrecht, Gerhard Gründer, Andrea Jungaberle, Henrik Jungaberle, Key competencies for psychedelic treatment in real-world mental health care settings, General Hospital Psychiatry, Volume 97, 2025, Pages 11-24, https://doi.org/10.1016/j.genhosppsych.2025.09.003.

probability of beneficial effects. [2] As a result, follow-up sessions will be extremely important for treatment and therefore should be structured. Patients may become vulnerable and expansive following administration; therefore, support should extend from weeks to months.

Clinical social workers should have received their master's degree from an accredited social work program, supervised clinical hours that are consistent across all states and licensure to serve patients in this phase of care. Clinical social workers should also be trained in evidence-based psychotherapy keyed to the specific intervention administered, this can be provided in the current social work curriculum for new students along with continuing education frameworks for clinical social workers in the current workforce. Training should include understanding the risk and adverse effects that may be experienced following administration.

Telehealth should not be the primary means of follow-up and communication. Depending on the patient's experience and reaction to the psychedelic substance telehealth services may not be appropriate.

General training/supervision:

The complexity of psychedelics being illegal at the federal level, yet legal for some states can cause an unclear understanding of the regulations. State laws and federal guidance do not explicitly recognize psychedelic preparation and integration within social work scope of practice. This can lead to credential confusion and ethical exposure. Workforce development, training and supervision must provide clear messaging with well-defined guidelines related to clear scope of practice protections and clinical social workers' ability to provide services with consideration for state licensing boards, regulatory agencies and liability insurance.

Training should include as many models as possible to include didactic, simulation- based, supervised practicums and apprenticeships. For social workers, supervision requirements should be consistent with the current supervision standards specified in the licensing statutes and regulatory standards of each jurisdiction and may include specifications for each level of social work practice or be universal, with one set of qualifications for all practice levels. [3]

Although interdisciplinary supervision may take place it is extremely important that clinical social workers receive supervision and consultation from another clinical social worker. Also, if clinical social workers are providing support to other disciplines, the clinical social worker should refer that supervisee to a member of her or his own profession for practice-specific supervision or consultation. [4]

Where standardized training is integrated into established social work curricula, a separate certification requirement may be unnecessary. Additionally, professional associations should provide continuing education and post-master's certificate programs to equip the existing

[2] Pilecki, B., Luoma, J. B., Bathje, G. J., Rhea, J., & Narloch, V. F. (2021). Ethical and legal issues in psychedelic harm reduction and integration therapy. *Harm Reduction Journal*, *18* (1), 40. https://doi.org/10.1186/s12954-021-00489-1

[3] *Best Practice Standards in Social Work Supervision*. (n.d.). https://www.socialworkers.org/Practice/NASW-Practice-Standards-Guidelines/Best-Practice-Standards-in-Social-Work-Supervision

[4] Id.

workforce to deliver this emerging treatment modality and to ensure that clinical social workers maintain current knowledge and competencies.

Federally Qualified Health Centers, Certified Community Behavioral Health Clinics, Rural Health Clinics, and Other Ambulatory Clinic Settings

Treatment should be provided in a controlled therapeutic setting under medical supervision. Controlled settings must include proper screenings, preparation, and support, and therefore deemed safer compared to unregulated settings such as underground therapies, retreats or ceremonial use. [5] Treatment programs involving indigenous communities may benefit from integrating specific indigenous and Western approaches to mental health care. [6]

A licensed medical provider should be onsite to provide a medical evaluation prior to drug administration and should be available onsite in the event of an emergency response. The interdisciplinary team should be present and may include but is not limited to medical, nursing, psychiatry, social work, psychology, other mental health or behavioral health providers and peers. A special feature of many clinical studies is the use of therapeutic dyads—historically and in many current studies a male-female team. [7] This form of co-therapy enhances safety and trust, enabling patients to engage in treatment with greater openness. From a psychodynamic perspective, the therapist dyad may also favor transference processes.[8] Working in pairs also provides additional support for both the patient and therapist(s) during treatment and for debriefing.

The implementation of this care delivery model may have an enormous impact on the current workforce's productivity and clinic capacity. Psychedelic-assisted therapy models require extended sessions, intensive emotional labor and the current payment systems do not reflect this intensity. The current policy discussions emphasize research and approval, with little information related to reimbursement parity. This can lead to the expansion of uncompensated or unstainable labor demands. Furthermore, the policy does not provide explicit recognition related to who should be performing the work which causes credential confusion and ethical exposure.

Psychedelic treatments must adhere to the same professional standards that govern all medical and psychotherapeutic practice.[9] Operations should clarify scope of practice, prevent workforce inequity, fund training, provide supervision, integration services and ensure reimbursement and labor protections match clinical intensity. Without these safeguards,

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[5] Caporuscio, C., Poppe, C., Gieselmann, A., & Repantis, D. (2025). Ethical issues with psychedelic-assisted treatments in psychiatry: A systematic scoping review. *Psychological Medicine*, *55*, e284. https://doi.org/10.1017/s0033291725101761

[6] Max Wolff, Hans Rutrecht, Gerhard Gründer, Andrea Jungaberle, Henrik Jungaberle, Key competencies for psychedelic treatment in real-world mental health care settings, General Hospital Psychiatry, Volume 97, 2025, Pages 11-24, https://doi.org/10.1016/j.genhosppsych.2025.09.003.

[7] Id.

[8] Id.

[9] Max Wolff, Hans Rutrecht, Gerhard Gründer, Andrea Jungaberle, Henrik Jungaberle, Key competencies for psychedelic treatment in real-world mental health care settings, General Hospital Psychiatry, Volume 97, 2025, Pages 11-24, https://doi.org/10.1016/j.genhosppsych.2025.09.003.

federal policy risks expanding treatment while further weakening the behavioral health workforce.

Technology-Enabled Scalability
AI technology and its use have increased and while it has some benefits when seeking to provide guidelines and standards related to emerging treatment, ethical considerations related to its use must be considered. Assessment, diagnosis, treatment and other services should not be delegated to AI technology; however, it may assist the provider with performing tasks for administrative support and use should comply with all applicable federal and state laws governing patient privacy that includes HIPAA and HITECH.

Thank you for your consideration of NASW's comments on this matter. Please do not hesitate to contact me at BBedney.nasw@socialworkers.org if you have any questions.

Sincerely,

Barbara Bedney

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NASW Chief of Programs