August 6, 2026

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

Submitted electronically to www.regulations.gov

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

Dear Administrator Engles,

The American Nurses Association (ANA) appreciates the opportunity to provide input to the Health Resources and Services Administration (HRSA) on the request for information (RFI) regarding workforce training and care delivery models for the administration of potential Food and Drug Administration (FDA)-approved psychedelic treatments in ambulatory settings.

ANA applauds the Administration's efforts to enable treatment availability for patients with serious mental illness. Collectively, nurses contribute to psychedelic care across a continuum of roles. Advanced practice registered nurses (APRNs), including psychiatric-mental health nurse practitioners (PMHNPs) and clinical nurse specialists (CNSs), may provide patients with psychedelic-assisted psychotherapy. Registered nurses (RNs), nurse practitioners (NPs), and CNSs may also participate in patient screening, preparation, treatment administration, patient monitoring, and integration support. As such, we urge HRSA to consider our comments on the following elements of the RFI:

- workforce training and education,
- supervision requirements,
- care delivery models, and
- technology scalability.

ANA represents the interests of the nation's over 5 million RNs through its constituent and state nursing associations, organizational affiliates, and individual members. ANA advances the nursing profession by championing nurses, fostering rigorous standards of nursing practice, promoting safe and ethical work environments, bolstering nurses' health and wellness, and advocating on the healthcare issues that impact both nurses and their patients. ANA seeks to ensure that nurses' voices, interests, and perspectives are represented and heard in policymaking discussions. Our

membership consists of both RNs and APRNs—nurse practitioners, clinical nurse specialists, certified nurse-midwives (CNMs), and certified registered nurse anesthetists (CRNAs).

Nursing is a profession grounded in critical thinking, scientific rigor, and evidence-based practice. Nurses are central to the delivery of high-quality care across many settings and serve in essential direct care, care coordination, research, and administrative leadership roles. Nurses form the backbone of the American health care system, providing and coordinating care, educating patients and the public, and offering counsel and emotional support to patients and their families. As the most trusted profession, nurses play a critical role in treating patients and influencing health behaviors.[1]

1. Training requirements for potential FDA-approved psychedelic treatments must be determined with nurse input on a drug-by-drug basis.

HRSA is seeking more information regarding training and educational requirements for persons who might administer potential FDA-approved psychedelics. Any potential FDA-approved psychedelics may have different modes of administration, dosing regimens, risk profiles, therapeutic indications, and indicated patient characteristics. **Accordingly, it is not yet possible to determine the specific training or education requirements for the individuals who will administer treatment, as those requirements will depend on substance-specific clinical trial data and the conditions established through FDA approval. However, at a minimum, individuals administering psychedelic treatments must be expected to have specialized training relating to the use of psychedelics.**

Currently, Oregon, Colorado, and New Mexico have passed legislation permitting regulated psilocybin use, although the scope of their programs and training requirements differ.[2, 3, 4] Oregon and Colorado both require state-approved facilitator training, but they do not require facilitators to hold a specific professional degree. In Oregon, individuals can become licensed psilocybin facilitators after completing an approved training program, regardless of whether they may have a medical, nursing, or therapy background.[5] Colorado similarly allows individuals without a medical license to become licensed psilocybin facilitators, however, the state's regulatory framework also includes pathways for licensed healthcare professionals to participate in certain regulated clinical

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[1] Brenan, M. (2026, January 12). Nurses continue to lead in honesty and ethics ratings. Gallup. https://news.gallup.com/poll/700736/nurses-continue-lead-honesty-ethics-ratings.aspx
[2] Oregon Revised Statutes. (2025). *Chapter 475A: Psilocybin regulation*. Oregon Legislative Assembly. https://www.oregonlegislature.gov/bills_laws/ors/ors475A.html
[3] *Natural Medicine Health Act of 2022*, Colo. Rev. Stat. §§ 12-170-101–12-170-117 (2025).
[4] S.B. 219, 57th Leg., 1st Sess. (N.M. 2025).
[5] Or. Admin. R. 333-333-3060 (2026).

settings.[6, 7, 8] Meanwhile, New Mexico is currently still implementing its medical psilocybin program model and is not yet treating patients, but the state plans to allow diagnostic clinicians to treat patients with psilocybin.[9] Under New Mexico's Medical Psilocybin Act, physicians and advanced practice providers, including NPs, who obtain a permit from the Department of Health may participate in the Medical Psilocybin Program once the program implementation is complete. Providers participating in the program will be responsible for evaluating patients, diagnosing qualifying medical conditions within their scope of practice and providing medical psilocybin services to eligible patients.[10] Currently, the New Mexico Department of Health is developing safety standards, treatment protocols, and establishing clinician psilocybin training requirements through the state's rulemaking process.

Even though there are pathways in both Colorado and Oregon for persons without a clinical degree to screen, prepare, and support a patient in psilocybin administration, the intravenous or intramuscular administration of ketamine—a dissociative—requires licensed healthcare professionals due to scope of practice. This shows that treatment requirements and training will have to differ across any potential FDA-approved psychoactive substances, depending on how they are administered. In order to determine the proper training and requirements for any potential FDA-approved psychedelic treatments, **HRSA must include expert clinicians, including APRNs and RNs, in any decision-making regarding each potential FDA-approved psychedelic substance when more information is available**. Additionally, HRSA can look to the psychedelic training programs in New Mexico, Colorado, and Oregon to serve as potential examples for any future training program development.

2. APRNs must be able to practice at the top of their license.

HRSA requests information regarding supervision requirements for psychedelic treatment across provider types. **Supervision requirements for APRNs are outdated and unnecessary, and ANA strongly supports full practice authority for all APRN roles.**[11] While many states allow APRNs to practice at the top of their license, supervision requirements in some states require that a physician sign off on an APRN's work. Notably, during the COVID-19 Public Health Emergency (PHE), the Trump Administration rightly relaxed these supervision requirements without any

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[6] *Natural Medicine Health Act of 2022*, Colo. Rev. Stat. §§ 12-170-101–12-170-117 (2025).
[7] S.B. 23-290, 74th Gen. Assemb., 1st Reg. Sess. (Colo. 2023).
[8] Colo. Rev. Stat. § 12-170-108
[9] New Mexico Department of Health. (2026). *Medical psilocybin program*. https://www.nmhealth.org/about/mcpp/mpp/
[10] S.B. 219, 57th Leg., 1st Sess. (N.M. 2025).
[11] American Nurses Association. (2020). *Principles for APRN full practice authority* (Updated February 2020; originally published June 2015). https://anaprodsite1.nursingworld.org/globalassets/docs/ana/ethics/principles-aprnfullpracticeauthority.pdf

discernible difference in patient care. Additionally, supervision requirements limit patient access to care, particularly in rural areas, across all sectors of care, where the only accessible healthcare provider may be an APRN. **As such, HRSA should ensure that PMHNPs and mental health CNSs can practice to the top of their licenses in both the administration and prescribing of potential FDA-approved psychedelics for serious mental illness.**

3. HRSA must ensure sustainable care delivery models for potential FDA-approved psychedelic treatments through fair reimbursement and stable telehealth access.

HRSA solicits information on care delivery models for potential future FDA-approved psychedelic treatments. For care delivery of psychedelic treatments to succeed, HRSA must work with the Centers for Medicare and Medicaid Services (CMS) to ensure that providers are properly reimbursed and ensure that any implementation systems are stable.

First, reimbursement for potential FDA-approved psychedelic treatments must be fair and reasonable. If reimbursement for potential FDA-approved psychedelic treatments is insufficient, it will discourage providers, such as APRNs, from offering potential FDA-approved psychedelic treatments. This is exemplified by Medicare needing to increase reimbursement for esketamine treatment in the CY 2026 Hospital Outpatient Prospective Payment System (HOPPS). Although esketamine is a dissociative rather than a classic psychedelic, esketamine therapy shares many of the same operational and mind-altering features as psychedelic-assisted treatments. For example, like regulated psilocybin services, esketamine is administered in a controlled setting under supervision, produces alterations in consciousness, necessitates post-treatment monitoring, and requires screening and preparation before treatment. Prior to the CY 2026 HOPPS, esketamine reimbursement in Medicare was so low relative to administration costs that it discouraged APRNs from offering the treatment, as providers had unreimbursed costs for administering esketamine to their patients. The original esketamine reimbursement amounts were particularly problematic for APRNS, as 42 C.F.R. § 414.56 requires APRNs to receive 15% less in Medicare reimbursement than physicians receive for the same service. This effectively created a barrier to access for patients in need of esketamine therapy, leading CMS to amend esketamine reimbursement in the CY 2026 HOPPS by placing esketamine treatment into ambulatory payment classifications 1512 and 1517, effectively raising payments for providers.

Furthermore, if APRNs are discouraged from administering a treatment due to low reimbursement cost, it will have a disproportionate impact on rural Americans. A shortage of practitioners continues to challenge rural areas, and APRNs remain critical in ensuring patient access to primary and other needed healthcare services.[12] Since NPs are more likely to work in rural areas than

[12] Neprash HT, Smith LB, Sheridan B, Moscovice I, Prasad S, Kozhimannil K. Nurse Practitioner Autonomy and Complexity of Care in Rural Primary Care. Medical Care Research and Review, December 2021, Vol. 78, No. 6, pp. 684–692. Published online July 29, 2020. https://doi.org/10.1177/1077558720945913

physicians, ensuring fair reimbursement for these services will help further HRSA's goal of improving rural health.[13, 14] **As such, HRSA must work with CMS to ensure that any FDA-approved psychedelics be reimbursed in a way that covers the costs of administration for all providers—particularly APRNs, who statutorily receive less reimbursement than their physician colleagues under the Medicare program.**

Additionally, HRSA solicits information regarding whether telehealth or remote monitoring are acceptable means for caring for patients during drug administration and whether telehealth is an appropriate way to screen patients for psychedelic therapies. **ANA urges HRSA and FDA to consult expert clinicians, including APRNs, on telehealth suitability for each individual future FDA-approved psychedelic treatment, due to the unique characteristics and risks of each treatment.** Further, if experts deem telehealth acceptable for screening or monitoring for a particular psychedelic treatment, patients insured by Medicare must be confident that their telehealth coverage will remain throughout the duration of their treatment, as the COVID-19 telehealth flexibilities extension is not permanent, and its end could pose a barrier to treatment and result in interrupted or incomplete treatments. **Therefore, ANA implores HRSA to work with Congress to use its authority to make the COVID-19 PHE telehealth flexibilities permanent, so these potential telehealth services can be covered for all patients.**

4. Human practitioners have the final authority on healthcare decisions.

HRSA seeks information regarding artificial intelligence (AI) and technology-enabled scalability, due to the labor-intensive nature of psychedelic therapy. Particularly, whether automated tools, such as AI technology, can support psychedelic treatment—patient screening, eligibility determination, risk stratification, and the detection of contraindications—whether human oversight should be required, and the limits of automated screening.

ANA believes that human practitioners must be highly involved in diagnosing patients and should have final authority on healthcare decisions. The future possibilities of AI and automated technology are endless, but HRSA must ensure that a human practitioner remains at the center of the process. Humans must get final say on diagnostics, and HRSA should require human oversight over AI in any treatment and in the usage of psychedelic treatments, especially because psychedelic treatments pose risks of adverse reactions and side effects. With or without AI tools, **removing supervision requirements for APRNs and ensuring proper reimbursement will**

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[13] Agency for Healthcare Research and Quality. (2012, January). *Primary care workforce facts and stats no. 3: Distribution of the U.S. primary care workforce* (AHRQ Pub. No. 12-P001-4-EF). U.S. Department of Health and Human Services. https://www.ahrq.gov/sites/default/files/publications/files/pcwork3.pdf

[14] Health Resources and Services Administration. (n.d.). *Mission*. Federal Office of Rural Health Policy. U.S. Department of Health and Human Services. Retrieved July 23, 2026, from https://www.hrsa.gov/rural-health/about-us/mission

ensure HRSA's ability to scale these treatments to due labor intensity by enabling more providers to offer psychedelic services, particularly in rural underserved areas.

ANA appreciates the opportunity to have this discussion and looks forward to continued engagement with CMS on shared priorities. Please contact Tim Nanof, ANA's Executive Vice President, Policy & Government Affairs at (301) 628-5166 or tim.nanof@ana.org with any questions.

Sincerely,

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Chief Nursing Officer

cc: Jennifer Mensik Kennedy, PhD, RN, NEA-BC, FAAN, ANA President
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