May 11, 2026

# Federal Momentum for Psychedelic and Emerging Behavioral Health Treatments: Key Legal Considerations

This Bulletin is brought to you by AHLA's Behavioral Health Practice Group.

May 11, 2026

**Alicia Macklin**, Hooper Lundy & Bookman PC | **Caitlin Callahan**, Hooper Lundy & Bookman PC

On April 18, 2026, the Trump administration issued an Executive Order, entitled *Accelerating Medical Treatments for Serious Mental Illness,* and launched a $139 million Advanced Research Projects Agency for Health (ARPA-H) initiative—both actions aimed at facilitating research on psychedelic drugs for mental health treatment.

Studies have indicated that psychedelic therapies, like psilocybin (the active ingredient in magic mushrooms) and MDMA (commonly known as ecstasy or molly), may hold the potential for treating serious mental illness (SMI), especially those conditions that have been resistant to other treatments. Experts urge caution, however, that further rigorous research is necessary to determine psychedelics' therapeutic potential, to study potential serious adverse effects, and to evaluate safe use conditions.

The Trump administration's announcements indicate a shift towards a loosening of regulatory constraints on the study of psychedelic products. Research into these potential treatments all but ceased following the passage of the U.S. Controlled Substances Act (CSA) and federal criminalization efforts during the War on Drugs. The shift in policy on psychedelics parallels the administration's recent efforts to expand access to medical marijuana. Following the White House Executive Order aimed at increasing medical marijuana research issued in December 2025, the Department of Justice announced on April 23, 2026 that certain marijuana products would be immediately reclassified from Schedule I to less restrictive Schedule III.

Though the Executive Order and ARPA-H funding will not result in immediate, regular consumer access to psychedelic treatment, they likely will accelerate and catalyze greater investment into research. Indeed, following the Order, the Food and Drug Administration (FDA) has already announced that it is issuing Commissioner's National Priority Vouchers to three companies studying psilocybin and methylone. The agency is also allowing a phase 1 clinical study of noribogaine hydrochloride (a derivative of ibogaine) and signaled plans to issue final guidance "imminently" to aid sponsors developing psychedelic products. Anticipating more activity in this space, it is important for health care lawyers to understand the direct implications these actions will have for FDA regulatory priorities, state compliance requirements, Drug Enforcement Administration (DEA) scheduling processes, and federal contracting practices.

## Accelerating Medical Treatments for Serious Mental Illness

The Executive Order directs coordinated federal action to accelerate research on and regulatory approval of psychedelic drugs for patients with SMI, with a particular emphasis on veterans.

The Executive Order sets out five components, each with legal and regulatory implications, that counsel should track:

1. **FDA Review Prioritization and Right to Try.** The FDA Commissioner is directed to issue Commissioner's National Priority Vouchers to psychedelic drugs that have received Breakthrough Therapy Designation and meet additional criteria. FDA leadership has publicly stated that drugs aligned with national priorities could receive approval in one to two months rather than the typical year-plus timeline. The administration's emphasis on speed does not displace the necessary safety and efficacy demonstrations for regulatory approval. Manufacturers, facilities, and researchers involved in clinical trials must ensure robust patient safeguards and clinical controls.

   The FDA and DEA are also directed to "facilitate and establish a pathway for eligible patients to access psychedelic drugs, including ibogaine compounds, under the Right to Try Act." The Right to Try Act provides access to investigational drugs outside of clinical trials for patients diagnosed with a life-threatening disease or condition who have exhausted all approved treatment options. The administration's decision to explicitly include psychedelic drugs as potentially eligible investigational drugs for use under The Right to Try Act raises unresolved questions, including about the scope of states' right to try statutes, institutional and manufacturer liability, and payer coverage.

2. **Department of Health and Human Services (HHS) Funding for Federal-State Collaboration.** ARPA-H is directed to allocate at least $50 million from existing funds to partner with states that have enacted or are developing programs to advance psychedelic drugs for SMI. This creates a compliance question for state-level programs: states seeking federal dollars will need to demonstrate their programs meet federal criteria, and the technical assistance and data-sharing components will implicate the Health Insurance Portability and Accountability Act (HIPAA), 42 C.F.R. Part 2 (for substance use disorder records), and potentially state-specific confidentiality

statutes.

3. **HHS and FDA Collaboration with Department of Veterans Affairs and the Private Sector.** HHS and FDA are directed to collaborate with the Department of Veterans Affairs and private sector entities to accelerate access, signaling expanded VA formulary consideration and potential public-private partnership structures that will need careful contractual and grant compliance analysis. The Executive Order also expressly directs these parties to increase data sharing, implicating the same privacy and confidentiality frameworks discussed above, including HIPAA and 42 C.F.R. Part 2.

4. **Timely Rescheduling.** The Attorney General, in consultation with HHS, is directed to initiate and complete rescheduling review for any Schedule I substance that successfully completes Phase 3 clinical trials for SMI. The Order directs product-specific rescheduling to occur as quickly as practicable for products ultimately approved under Section 505 of the Federal Food, Drug, and Cosmetic Act.

One critical caveat: the Executive Order does not legalize any psychedelic drug. Ibogaine, the only psychedelic therapy specifically identified in the Order, remains categorized in Schedule I under the CSA, meaning it is a drug with a high potential for abuse and for which there exists no currently accepted medical use. Products still require FDA approval through the Section 505 new drug pathway. The Executive Order accelerates and prioritizes that approval process but does not short-circuit it.

## ARPA–H EVIDENT Initiative: $139 Million for Behavioral Health Measurement Science

In furtherance of the Order, ARPA-H announced the first set of research teams for its Evidence-Based Validation & Innovation for Rapid Therapeutics in Behavioral Health (EVIDENT) initiative. EVIDENT will be the implementing mechanism for the Order's $50 million federal-state matching obligation. And ARPA-H has announced allocation of considerably more funds than contemplated by the Order: EVIDENT will fund up to $139.4 million across 13 initial research teams, with additional awards to follow on a rolling basis.

The initiative's stated purpose is to solve a fundamental problem that has hampered both drug approval and coverage decisions: the absence of objective, scalable measures of treatment response in behavioral health. Current clinical trials rely on subjective rating scales and delayed feedback. EVIDENT is designed to generate FDA-ready clinical endpoints for rapid-acting therapies, including psychedelics, neuromodulation, and digital interventions, that can support both new product applications and real-world clinical deployment.

The 13 initial performer teams present a picture of the initiative's scope, focused on understanding, measuring, and improving mental and behavioral health. The awards emphasize investment in researching:

- Objective biomarkers of mental health states and treatment response
- Neuromodulation, microbiome, and psychedelic-assisted interventions
- Integration of new types of data, including genomic and digital (i.e., wearable device) data
- Rapid and scalable evaluation of treatment efficacy in real-world settings

ARPA-H awards under EVIDENT are contracts, not grants, with milestone-based disbursement. This affects both programmatic flexibility and how institutions account for and comply with federal funding requirements.

## What's Next?

The Executive Order underscores that expanded federal engagement in psychedelic research and treatment development carries significant legal and compliance implications for states, providers, manufacturers, and private partners. Counsel should evaluate how state legalization regimes align with federal funding eligibility requirements, monitor clients' continued compliance with DEA controlled substances restrictions, and ensure new drug development efforts meet FDA's rigorous safety, efficacy, and patient-protection standards. The Executive Order also highlights the substantial uncertainty surrounding expanded access outside clinical trials, including under the Right to Try Act, and the limits of accelerated FDA approval in securing payer coverage absent objective treatment endpoints. As federal-state and public-private collaboration increases, counsel should further monitor professional licensing guidance and prepare for heightened compliance obligations related to data sharing, privacy, Institutional Review Board oversight, and federal contractor standards.

**ARTICLE TAGS**

Behavioral Health Practice Group  Behavioral Health  Life Sciences



1099 14th Street NW, Suite 925, Washington, DC 20005 | P. 202-833-1100
**For payments**, please mail to P.O. Box 79340, Baltimore, MD 21279-0340