Editor's Note: The following is excerpted from a blog post by Barbara J. Zabawa, president of the Center for Health and Wellness Law, LLC. The blog post originally appeared on the website of the International Foundation's sister organization, the Wellness Alliance.

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Legal Considerations When Covering Psychedelics

hat are some legal considerations for employers and plan sponsors as they encounter requests to offer psychedelic medicine to treat depression and improve employee mental well-being?

Parity Issues

If psychedelics, especially those that are legal, are available but not offered by employee benefit plans, could plan sponsors be accused of discriminating against employees with mental illness? Group health plans that cover weight loss drugs like Ozempic[®] but do not cover psychedelic drugs to treat treatment-resistant depression may need to demonstrate that the method it used to decline prescription drug coverage for a mental health disorder is no more restrictive than the method it uses to cover a drug to treat diabetes and/or obesity.¹

Provider Standards

Psychedelic administration should occur alongside guided therapy from highly trained therapists. In the clinical trials for 3,4-methylenedioxymethamphetamine (MDMA) to treat posttraumatic stress disorder (PTSD), the participant drug is administered by trained therapists who guide the participant's experience through scripted sessions that also allow for improvisation.² Thus, for psychedelic treatment to be effective and safe, plan sponsors should ensure that the individuals who administer the psychedelic drugs are properly trained. Failing to use properly trained practitioners to administer the drugs and provide the requisite therapy could

increase the chance of inappropriate use, abuse, harm and therefore liability to the employer. Employers will need some way to verify that the individuals administering the psychedelics are properly trained and have adequate liability insurance for themselves. Employers should also ensure that their own liability insurance covers the use and administration of psychedelic treatment to employees.

State vs. Federal Legal Compliance

Some state and local governments may allow for psychedelic use for depression before federal law permits it. For example, the State of Oregon has decriminalized medical and (effectively) recreational use of psilocybin. Municipalities including Oakland, Santa Cruz, and Arcata, California; Ann Arbor, Michigan; and Somerville, Cambridge, and Northampton, Massachusetts have passed legislation decriminalizing psychedelics.³

Legalizing more psychedelic drugs for medical use could follow a similar pattern as legalization of marijuana. Marijuana is still illegal at the federal level, but many states have legalized it. Psychedelic legalization seems to be following a similar path, with state and local governments taking action before the federal government. Employers that conduct business in states or localities that permit the use of psychedelics to treat depression may still need to consider federal law, specifically the Controlled Substances Act. Employers will need to weigh the legal risk of violating federal law while trying to help employees who may need mental health treatment with psychedelics.

Offering Psychedelics Through an EAP or **On-Site Clinic May Trigger HIPAA/ACA and HSA Compliance Issues**

The recent Food and Drug Administration (FDA) approval of Spravato requires that people taking the drug be monitored in a doctor's office for at least two hours and have their experi-

ence entered into a registry.⁴ Indeed, according to one study, "training and clinical oversight is necessary to ensure safety and also therapeutic efficacy for this divergent class of treatments."5 Thus, offering psychedelics such as ketamine should be more than just listing it on the group health plan's formulary. Plans that consider offering this treatment for depression and/or PTSD will also need to ensure that proper clinical protocols are followed, including ensuring that a trained clinician oversees the drug's administration and use.

If an employer offers this treatment through an employee assistance program (EAP) or on-site clinic, this more involved treatment would likely represent significant benefits in the nature of medical care, thus requiring employers to comply with the Health Insurance Portability and Accountability Act (HIPAA) and the Affordable Care Act (ACA) market reforms if offered through an EAP, and the treatment could jeopardize health savings account (HSA) eligibility for employees.

The legal issues above are just some examples that plan sponsors should consider as they are approached by various stakeholders about offering psychedelic treatment for employees suffering from depression or PTSD. This is an evolving area of law, and employers should engage competent legal counsel to help them navigate their way to a benefit plan that makes the most sense for them and their employees.

Endnotes

1. 88 Fed. Reg. at 51569 (August 3, 2023).

2. "What's Next for MDMA in Psychiatry?" Nature, Vol. 616 (April 20,

3. J. S. Siegel, M.D. et al. "Psychedelics Drug Legislative Reform and Legalization in the US" *JAMA Psychiatry*. (January 1, 2023).

4. "Veterans Agency to Offer New Depression Drug, Despite Cost and

Safety Concerns," *The New York Times.* (June, 21, 2019.)
5. J. S. Siegel, M.D. et al. "Psychedelics Drug Legislative Reform and Legalization in the US" *JAMA Psychiatry.* (January 1, 2023).