COMMENTARY

Beyond Cannabis in the Garden State: New Jersey's Psilocybin Behavioral Health Access and Services Act

While it's unclear whether the act as written will become law in New Jersey, it will likely serve as the foundation of a future statutory and regulatory psilocybin program in the state. As such, the act merits an in-depth review and analysis in its current state.

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Legislation

By Joseph M. Shapiro, Michael F. Schaff and Daniel T. McKillop | March 27, 2023 at 11:00 AM

Psilocybin is a naturally occurring compound found in over 200 species of mushroom and is currently regulated as a Schedule I drug with "no currently accepted medical use and a high potential for abuse" pursuant to the federal Controlled Substances Act (CSA). Notwithstanding that classification and description, a growing body of scientific and medical studies and trials indicates that psilocybin-assisted therapies provide benefits to those suffering from various health conditions. In fact, the U.S. Food and Drug Administration (FDA) itself has twice designated psilocybin as a "breakthrough therapy," meaning clinical evidence indicates that psilocybin therapy demonstrates substantial improvement over other available therapies for both major depressive disorder and treatment-resistant depression.

Given these findings, an increasing number of foreign and domestic stakeholders continue to act and advocate for expanded access to psilocybin therapies. For example, Australia's equivalent to the FDA announced that medicines containing psilocybin can be prescribed for the treatment of certain mental health conditions starting July 2023, and Oregon recently began accepting applications for psilocybin business licensure. Litigation is another pathway being used to facilitate psilocybin access. In a leading U.S. case, *Aggarwal v. U.S. Drug Enforcement Administration,* No. 22-1718 (9th Circuit), petitioner Dr. Sunil Aggarwal seeks to secure access to psilocybin for administration to his patients by compelling the U.S. Drug Enforcement Administration (DEA) to follow protocol and properly consider rescheduling psilocybin from Schedule I to Schedule II of the CSA.

New Jersey is now building on its successful enactments of medical and adult-use cannabis laws and is working toward facilitating psilocybin access via similar legislation. In June 2022, Senate President Nicholas Scutari introduced a bill titled the "Psilocybin Behavioral Health Access and Services Act" (S. 2934), and an identical companion bill was introduced in the Assembly in December 2022 (A. 4911) by Assemblymen Raj Mukherji, Herb Conaway Jr. and James J. Kennedy

(collectively, the act). While it's unclear whether the act as written will become law in New Jersey, it will likely serve as the foundation of a future statutory and regulatory psilocybin program in the state. As such, the act merits an in-depth review and analysis in its current state.

An Overview of the Act

The "personal use" aspects of the act have garnered much attention, e.g., growing psilocybin-containing mushrooms at home. However, the act is chiefly designed to create licensing and operational structures and protocols to facilitate the production, testing, and administration of psilocybin products in "safe, controlled environments" designed to foster "supported psilocybin experiences to alleviate distress, provide preventative behavioral health care, and foster wellness and personal growth."

To accomplish these complex goals, an 18-member "Behavioral Health Access and Services Advisory Board" composed of governmental agency officials and governor appointees would be established within the New Jersey Department of Health (DOH). The board would be tasked with providing recommendations to the DOH, the governor, and the Legislature regarding the implementation of the act. Using the board's recommendations, within 18 months of enactment, the DOH would issue and begin accepting (but not yet approving) license applications from prospective manufacturers, service centers, facilitators, and testing laboratories, as well as permit applications from prospective psilocybin workers. Manufacturer "microbusiness" licenses will be available to entities that show that at least 51% of their owners, directors, officers and employees live in the municipality (or in a bordering municipality) where the microbusiness is or will be located, that have 10 or fewer total employees, and will operate within no more than 2,500 square feet. The DOH would also establish a "social opportunity program" to facilitate licensure of prospective manufacturers, service centers, service facilitators, and testing laboratories who are at least 51 owned or controlled by individuals who have lived in a DOH-designated distressed area for five of the past 10 years, have more than 10 full-time employees and half of which currently live in a distressed area or meets any other eligibility criteria for the social opportunity program as may be established by the DOH.

Under the act, there are no specific residency requirements to apply for or obtain licenses or permits, except for the act's microbusiness and social equity provisions. However, there are restrictions on the number of licenses one could hold. One person could possess multiple service center licenses and could also hold both a manufacturer license and one or more service center licenses. One person could not, however, hold a financial interest in more than one manufacturer or more than five service centers. Applicants for manufacturer, service center, and testing laboratory licenses would require demonstration of site control and certain local approvals, and all applicants would be required to undergo criminal background checks.

Unlike New Jersey's cannabis programs, counties and municipalities would not be permitted to "opt-out" or to otherwise ban psilocybin product manufacturers or psilocybin service centers from operating in their jurisdictions. Counties and municipalities would also be prohibited from imposing any taxes or fees on licensees regarding the manufacture or sale of psilocybin products or the provision of related services. However, counties and municipalities may adopt ordinances to impose "reasonable regulations" on the operation of manufacturers and service centers within their borders.

Once approved, licensees and permittees would operate to manufacture psilocybin, test psilocybin, and in the case of service centers and facilitators, to provide "psilocybin services" to clients. Psilocybin services would generally be provided by a facilitator on the premises of a service center, and would be composed of: (1) a "preparation session" (the initial screening to verify the client's age and screen for any signal that psilocybin is contraindicated for the client); (2) an "administration session" (providing psilocybin to the client by a facilitator who guides the client throughout the session); and (3) an optional "integration session" (during which a facilitator works with the client to process the results of the administration session). Co-location of manufacture and service center operations would be permitted under the act, although licensees would likely be required to segregate those activities into separate areas of the premises.

A Closer Review of Specific Provisions

Several specific provisions of the act incorporated within the above general review merit closer attention and are discussed below.

Natural and synthetic psilocybin production.

The act broadly defines “psilocybin” as both “psilocybin or psilocin.” It is important to consider this definition in more detail and to delve briefly into some chemistry here. Psilocybin is a prodrug of the compound psilocin. This means that once psilocybin is metabolized in our bodies, it is converted to its pharmacologically active metabolite psilocin. In short, psilocin is primarily responsible for the psychedelic effects of psilocybin. Therefore, under the act’s broad definition of “psilocybin,” manufacturers could produce a variety of products which include psilocybin, the separate (and potentially more bioavailable) compound psilocin, or a combination of both. The act also broadly defines the “manufacture” of psilocybin products, and manufacturers could produce psilocybin products “from substances of natural origin,” “independently by means of chemical synthesis,” or through a combination of both methods. So, whereas another state (Oregon) has specifically limited manufacturers’ source of psilocybin to a single species of psilocybin-containing mushroom, the act in its current form would permit manufacturers to produce psilocybin products from either or both natural and synthetic sources.

The act’s broad definitions of “psilocybin” and “manufacture” would together foster opportunities for innovation in the production and ultimate administration of “psilocybin products.” However, the act also specifically protects client access to “natural” psilocybin products by prohibiting the DOH from: (1) requiring manufacture by chemical synthesis; (2) preventing the use of naturally grown mushrooms; or (3) requiring the use of patented products or procedures. While there exists a pervasive “natural” versus “synthetic” debate within psychedelics generally, the act appears to balance those competing interests by preserving client access to “natural” and non-patented psilocybin while simultaneously permitting synthetic production.

Diverse public board membership.

There are diverse perspectives on the proper means of implementing a psychedelics-based program like the one proposed by the act, and those perspectives are not always in harmony. To this point, the act would require the governor to appoint public members to the board who possess a wide range of expertise in a variety of areas. Most of the 18-member board would be made up of 12 public members whose expertise shall include: (1) clinical dependence; (2) community-based public health services; (3) a licensed psychologist engaged in behavioral, mental and emotional health; (4) a licensed physician; (5) a public health academic; (6) scientific research regarding the using of psychedelic compounds in clinical therapy; (7) mycology, ethnobotany, or psychopharmacology; (8) confronting veterans’ issues; (9) traditional, cultural, and religious uses of psilocybin; (10) emergency medical services; (11) harm reduction and drug policy; and (12) racial and economic equity and health care access. Presumably, the act’s requirement that this roster of individuals serve on the board is an attempt to keep the DOH adequately informed as it works to ensure that psilocybin services “become and remain a safe, accessible, and affordable treatment option” in the state.

In-home administration and remote preparation and integration sessions.

The act envisions in-home administration of psilocybin under certain circumstances. Facilitators would be authorized to provide psilocybin services in a private residence in New Jersey if, for medical reasons, a client is unable to travel to a service center. The DOH would determine standards for when in-home administration sessions may be permitted and develop related protocols, guidelines, and best practices. Further, while the act requires that psilocybin administration occur in person, both the initial preparation session and the optional integration session may be accomplished remotely. “Remotely” arguably includes telephone and video conferencing as “any appropriate form of communication technology”

may be as authorized by the DOH. The act's in-home administration and remote preparation and integration provisions, if liberally implemented, could increase access and affordability for those in the state who may be in most need of psilocybin services.

Personal use provisions.

The act would permit liberal "personal use" of psilocybin, which would include both cultivating and processing psilocybin at home. The act only requires that psilocybin produced at home be kept on the grounds of a private home and secure from access by minors. The act would also permit adults to assist others with cultivating and processing psilocybin, and for adults to distribute up to 4 grams of psilocybin without consideration. Given the potential ramifications of these personal use provisions, and the fact that the Legislature has not allowed for home cultivation of cannabis in New Jersey, these provisions will be closely scrutinized by legislators and stakeholders alike as the act makes its way through the legislative process.

Conclusion

New Jersey's past success legalizing and regulating controlled substances, combined with growing national and international legislative momentum favoring access to psilocybin, makes it likely that the act or similar legislation will proceed in the Garden State. However, the final legalization of psilocybin and other efficacious psychedelic compounds will require stakeholders to continue to educate legislators (and each other) on the nature of these compounds and the roles they should play both in New Jersey health care programs and in society.

The foregoing content is for informational purposes only and does not constitute legal advice or create an attorney-client relationship. Illegal possession, use, distribution, and/or sale of psilocybin is a federal and state crime.

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