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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 1959 Session of 2021

INTRODUCED BY PENNYCUICK, O'MARA, ISAACSON, T. DAVIS, SCHLOSSBERG, HENNESSEY, LEWIS DELROSSO, GUENST, POLINCHOCK, DOWLING, HAMM, SANCHEZ, SAPPEY, SIMS, O'NEAL, SHUSTERMAN, BOBACK, N. NELSON, BERNSTINE, E. NELSON AND McNEILL, OCTOBER 12, 2021

REFERRED TO COMMITTEE ON HEALTH, OCTOBER 12, 2021

AN ACT

Providing for research and clinical studies of psilocybin, for duties of Department of Health, for duties of institutional review boards, for duties of authorized psilocybin manufacturers, for duties of approved investigators and for reports.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. Short title.

This act shall be known and may be cited as the Public Health Benefits of Psilocybin Act.

Section 2. Declaration of purpose.

The General Assembly finds and declares as follows:

(1) Our nation is experiencing an unprecedented mental health crisis.

(2) In 2021, more than 47,000,000 Americans were suffering from a mental illness, including more than 1,800,000 adults in this Commonwealth, which represents 18% of this Commonwealth's adult population.

(3) Of the 1,800,000 adults in this Commonwealth who suffer from a mental illness, more than 727,000 suffered from a substance use disorder and more than 416,000 suffered from serious thoughts of suicide.

(4) For veterans in the United States, the nationwide suicide rate is one and a half times greater than nonveterans.

(5) In the United States, 22 veterans die by suicide each day.

(6) This Commonwealth ranks amongst the worst states in the nation in treating mental health conditions with approximately 480,000 adults in this Commonwealth reporting an unmet need for their mental health conditions in 2021.

(7) Common barriers to entry for mental health treatment include the lack of adequate health insurance, shortfalls in psychiatrists and other mental health professionals, lack of available treatment types and insufficient finances to cover health care costs.

(8) The Commonwealth has a history of providing insufficient funding for mental health care, despite the continuing escalation of the mental health crisis, which has now been exacerbated by the COVID-19 pandemic.

(9) While the full extent of the mental health consequences of the COVID-19 pandemic are not yet fully understood, a study conducted by Dartmouth University found that since the onset of the pandemic, rates of depression and anxiety have soared amongst college-age adults.

(10) Similarly, the United States Department of Health and Human Services Centers for Disease Control and Prevention has noted increases in the number of adults seeking mental

health care, dealing with anxiety and experiencing symptoms of depressive episodes.

(11) Consequently, this Commonwealth is in desperate need of innovative and cost-effective mental health treatment to combat this significant public health crisis.

(12) A growing body of research suggests that psilocybin, administered in a controlled setting, may be the most effective tool at our disposal to combat this public health crisis.

(13) Studies conducted by world-renowned medical institutions indicate that psilocybin has shown efficacy, tolerability and safety in the treatment of mental health conditions, including, but not limited to, addiction, depression, anxiety disorders and end-of-life psychological distress.

(14) The United States Food and Drug Administration, based on the success of the studies on the efficacy of psilocybin, has granted a "breakthrough therapy" designation for use of psilocybin to treat depression.

(15) Numerous jurisdictions in the United States have reformed their laws to decriminalize or further research the full scope of the public health benefits of psilocybin.

(16) It is the duty of the Department of Health to protect the health of the people of this Commonwealth and to determine and employ the most efficient and practical means for the prevention and suppression of disease.

(17) This Commonwealth, including this Commonwealth's substantial veteran community, will benefit from establishing a psilocybin regulatory system to combat the worsening mental health crisis.

(18) Additional research is required to determine the efficacy of psilocybin and how to maximize its public health benefits at the lowest cost with the goal of making the treatment broadly available if clinical studies prove successful.

(19) Achieving the optimal public health benefit of psilocybin requires the Commonwealth to invest in and facilitate research using naturally grown psilocybin mushrooms, which would be infeasible if conducted through private funding.

(20) Our federalist system of government allows states to experiment and compete in the marketplace of ideas to achieve the most efficient and practical solutions to the problems of constituents.

(21) This act provides a framework for research in this Commonwealth to discover innovative methods to optimize the public health benefits of psilocybin.

Section 3. Definitions.

The following words and phrases when used in this act shall have the meanings given to them in this section unless the context clearly indicates otherwise:

"Approved investigator." A medical school, medical research institute, institution of higher education or medical center in this Commonwealth that provides medical care to veterans or community clinics and has a qualified and appropriate lead investigator for the purpose of conducting clinical studies under this act.

"Authorized psilocybin manufacturer." An entity approved by the department to plant, grow and cultivate natural psilocybin mushrooms solely for use in clinical studies conducted under

this act.

"Department." The Department of Health of the Commonwealth.

"Institutional review board." An appropriately constituted group that has been established by the department to review and monitor biomedical research involving human subjects under section 5(a)(1).

"Lead investigator." An individual who meets all of the following criteria:

(1) The individual conducts a clinical study of psilocybin under this act, including administering psilocybin or managing related therapeutic protocols, or in the event of a clinical study conducted by a group of individuals, is the manager of the group of individuals for the clinical study.

(2) The individual has the association and approval of an institutional review board to conduct a clinical study of psilocybin under this act.

"Psilocybin." Psilocybin and other compounds that cause nonordinary states of consciousness via serotonin 2A receptor agonism.

"Psilocybin-assisted therapy." The use of a therapeutic protocol involving one or more therapy sessions in which the research subject who receives therapy does so after ingesting psilocybin.

Section 4. Research and clinical studies of psilocybin.

(a) Evaluation.--The department shall evaluate and determine the efficacy and cost-benefit optimization of psilocybin and psilocybin-assisted therapy in the treatment of mental health conditions and traumatic brain injury as conducted in clinical studies by approved investigators. The department's evaluation under this subsection shall include consideration for individual

health outcomes and public health outcomes, including methods to reduce cost and increase scalability of treatment.

(b) Clinical studies.--

(1) An approved investigator may conduct a clinical study of psilocybin under this act for any of the following conditions:

(i) Post-traumatic stress disorders.

(ii) Depression.

(iii) Anxiety.

(iv) Suicidal ideation.

(v) Eating disorders.

(vi) Bipolar disorders.

(vii) Chronic pain.

(viii) Migraines.

(ix) Substance use disorders.

(x) Traumatic brain injury.

(2) An approved investigator shall use a therapeutic dose of psilocybin for each participant in a clinical study of psilocybin conducted under this act.

(3) An approved investigator may include a control group for any of the following in a clinical study of psilocybin conducted under this act:

(i) Therapeutic dose levels.

(ii) A comparison of naturally grown psilocybin mushrooms and synthetic psilocybin.

(iii) Therapeutic protocols.

(iv) Any other similar comparative purpose to determine the efficacy and cost-benefit maximization of psilocybin to treat mental health.

(4) A clinical study of psilocybin conducted under this

act may include any of the following:

(i) A participant who is deemed healthy by a lead investigator and is accompanied by a family member who suffers from a condition specified under paragraph (1).

(ii) The administration of psilocybin in a supervised group setting. If the administration of psilocybin involves a participant under subparagraph (i), the participant shall be accompanied by a family member who suffers from a condition specified under paragraph (1).

(iii) The administration of psilocybin in a controlled, outdoor setting.

Section 5. Duties of department.

(a) Duties.--The department shall have the following duties:

(1) Establish an institutional review board for the purposes specified under section 6.

(2) When allocating funds for clinical studies of psilocybin conducted under this act, prioritize the approval of clinical studies specific to the treatment of veterans and retired first responders and their family members.

(3) Collect data from clinical studies of psilocybin conducted under this act that seek to determine the efficacy and cost-benefit optimization of psilocybin and psilocybin-assisted therapy in accordance with the purposes of this act.

(4) Identify and authorize two or more qualified entities to plant, grow and cultivate natural psilocybin mushroom product solely for use in the clinical studies of psilocybin conducted under this act.

(5) Adopt standards as the department deems necessary for an entity to be qualified for consideration as an

authorized psilocybin manufacturer.

(6) Adopt standards as the department deems necessary for testing and confirming the quality and dosages of psilocybin certified by an authorized psilocybin manufacturer.

(7) Authorize as many qualified entities as deemed necessary to carry out the clinical studies of psilocybin conducted under this act.

(8) Adopt standards and testing procedures for ensuring consistent quality and dosages of natural psilocybin mushrooms for clinical studies of psilocybin conducted under this act.

(b) Preferences.--The department may give preference for the funding of clinical studies of psilocybin that utilize specific psilocybin-assisted therapy protocols and psilocybin dosages if the department reasonably determines that the clinical studies would add to the available research literature that is relevant for the purposes of this act.

(c) Coordination.--The department may coordinate with clinicians conducting studies of psilocybin in other states to collect unpublished data and results.

Section 6. Duties of institutional review boards.

(a) Duties.--An institutional review board shall have the following duties:

(1) Oversee proposed clinical studies of psilocybin conducted under this act.

(2) Assist lead investigators at sites lacking formal institutional review board oversight.

(3) Protect the rights, safety and welfare of human subjects under this act.

(b) Psilocybin research.--An institutional review board may approve, require modifications in order to secure approval or disapprove psilocybin research.

Section 7. Duties of authorized psilocybin manufacturers.

An authorized psilocybin manufacturer shall certify, in writing, to the department and an approved investigator that the authorized psilocybin manufacturer meets all of the following criteria:

(1) The authorized psilocybin manufacturer has complied with the department's required standards and testing procedures to ensure consistent quality and dosages.

(2) The authorized psilocybin manufacturer's psilocybin mushrooms meet the required specifications for each clinical study of psilocybin.

Section 8. Duties of approved investigators.

(a) Contracts.--An approved investigator shall contract directly with an authorized psilocybin manufacturer for the purchase of natural psilocybin mushrooms in accordance with the specifications requested by the lead investigator of each clinical study of psilocybin.

(b) Synthesized psilocybin.--An approved investigator may acquire synthesized psilocybin for comparative research with natural psilocybin mushrooms by contracting directly with the manufacturer of the synthesized psilocybin. An authorized psilocybin manufacturer may not provide synthesized psilocybin under this subsection.

Section 9. Reports.

(a) Quarterly reports.--The department shall prepare and submit quarterly reports on the progress of the clinical studies of psilocybin conducted under this act to the Governor, the

Lieutenant Governor and each member of the General Assembly.

(b) Final reports.--No later than January 1, 2025, the department shall prepare and submit a final report to the Governor, the Lieutenant Governor and each member of the General Assembly. The final report shall contain all of the following:

(1) The results of the clinical studies of psilocybin conducted under this act.

(2) An analysis of the current state of available research related to psilocybin and similar compounds.

(3) An overview of current Federal laws related to psilocybin and similar compounds.

(4) An overview of laws in other states related to psilocybin and similar compounds, including an analysis of the successes and challenges of the laws in other states with a particular focus on the regulatory framework for research or the implementation of psilocybin-assisted therapy developed in other states.

(5) An overview of proposed Federal, State, local and other jurisdictional laws or ordinances, including proposed laws or ordinances outside of the United States, related to psilocybin and similar compounds.

(6) Recommendations for legislative actions or other actions to enact a framework for further research of psilocybin and similar compounds, including a consideration of systems adopted by other states and the medical marijuana research framework already established in this Commonwealth.

(7) Recommendations for legislative actions or other actions for the implementation of a regulatory system governing the use of psilocybin and psilocybin-assisted therapy with the goal of minimizing cost and maximizing the

public health benefit of treatment.

(c) Confidentiality.--The department shall ensure protected health information collected during a clinical study of psilocybin conducted under this act or for a report under this section remains confidential and does not personally identify an individual.

Section 10. Effective date.

This act shall take effect in 60 days.