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LEGISLATIVE REFERENCE BUREAU

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No._____

Legislative Reference Bureau

AN ACT

Providing for research and clinical studies of psilocybin and psilocybin-assisted therapy.

INTRODUCED _____ **20**_____

By _____ **District NO.** ____

By _____ **District NO.** ____

By _____ **District NO.** ____

By _____ **District NO.** ____

See next page for additional co-sponsors.

☐ **Prior Session** _____

Referred to Committee on

Date_____**20**___

Reported_____**20**___

As Committed-Amended

Recommendation

_____

By Hon._____

AN ACT

Providing for research and clinical studies of psilocybin and psilocybin-assisted therapy.

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 Psilocybin Data 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 for nonveterans.

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

(6) This Commonwealth ranks among 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) 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.

(9) 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.

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

(11) 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.

(12) 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.

(13) 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.

(14) 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.

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

(16) 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.

(17) 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.

(18) 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.

(19) 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:

"Academic research institution." An institution affiliated with a hospital or an institution of higher education that conducts health care research in this Commonwealth.

"Advisory committee." The Health Research Advisory Committee established in section 903(b) of the act of June 26, 2001 (P.L.755, No.77), known as the Tobacco Settlement Act.

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

"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 and psilocybin-assisted therapy.

The department, in collaboration with the advisory committee, shall contract with at least one academic research institution for the purpose of collecting and studying 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 the academic research institution. The data collected under this section shall include a consideration for individual health outcomes and public health outcomes, including methods to reduce cost and increase scalability of treatment. In conducting the clinical studies for the purposes of this section, the academic research institution shall focus on all of the following conditions:

(1) Post-traumatic stress disorders.

(2) Depression.

(3) Anxiety.

(4) Suicidal ideation.

(5) Eating disorders.

(6) Bipolar disorders.

(7) Chronic pain.

(8) Migraines.

(9) Substance use disorders.

(10) Traumatic brain injury.

(11) Any other necessary condition as determined by the department, in collaboration with the advisory committee, or the academic research institution.

Section 5. Reports.

(a) Reports.--The department, in collaboration with the advisory committee, shall issue interim reports every 180 days beginning 180 days after the effective date of this section on the data collected from the academic research institution under section 4 and a final report by December 31, 2025. The final report shall contain all of the following:

(1) The results of the clinical studies of psilocybin conducted by the academic research institution.

(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.

(b) Submission.--The department, in collaboration with the advisory committee, shall submit the interim reports and the final report under subsection (a) to all of the following:

(1) The President pro tempore of the Senate.

(2) The Speaker of the House of Representatives.

(3) The Majority Leader of the Senate.

(4) The Majority Leader of the House of Representatives.

(5) The Minority Leader of the Senate.

(6) The Minority Leader of the House of Representatives.

(7) The chair and minority chair of the Appropriations Committee of the Senate.

(8) The chair and minority chair of the Appropriations Committee of the House of Representatives.

(9) The chair and minority chair of the Health and Human Services Committee of the Senate.

(10) The chair and minority chair of the Health Committee of the House of Representatives.

(11) The chair and minority chair of the Human Services Committee of the House of Representatives.

(12) The chair and minority chair of the Veterans Affairs and Emergency Preparedness Committee of the Senate.

(13) The chair and minority chair of the Veterans Affairs and Emergency Preparedness Committee of the House of Representatives.

(c) Confidentiality.--The department shall ensure that protected health data collected from the academic research institution under section 4 remains confidential and does not personally identify an individual in the interim reports and the final report under subsection (a).

Section 6. Effective date.

This act shall take effect in 60 days.