
THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 2421 Session of
2022

INTRODUCED BY PENNYCUICK, O'NEAL, RYAN, SCHLOSSBERG, SCHLEGEL
CULVER AND ROZZI, MARCH 16, 2022

REFERRED TO COMMITTEE ON HEALTH, MARCH 16, 2022

AN ACT

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

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

5 Section 1. Short title.

6 This act shall be known and may be cited as the Psilocybin
7 Data Act.

8 Section 2. Declaration of purpose.

9 The General Assembly finds and declares as follows:

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

12 (2) In 2021, more than 47,000,000 Americans were
13 suffering from a mental illness, including more than
14 1,800,000 adults in this Commonwealth, which represents 18%
15 of this Commonwealth's adult population.

16 (3) Of the 1,800,000 adults in this Commonwealth who
17 suffer from a mental illness, more than 727,000 suffered from
18 a substance use disorder and more than 416,000 suffered from

1 serious thoughts of suicide.

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

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

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

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

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

21 (9) Similarly, the United States Department of Health
22 and Human Services Centers for Disease Control and Prevention
23 has noted increases in the number of adults seeking mental
24 health care, dealing with anxiety and experiencing symptoms
25 of depressive episodes.

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

29 (11) A growing body of research suggests that
30 psilocybin, administered in a controlled setting, may be the

1 most effective tool at our disposal to combat this public
2 health crisis.

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

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

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

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

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

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

30 (18) Our federalist system of government allows states

1 to experiment and compete in the marketplace of ideas to
2 achieve the most efficient and practical solutions to the
3 problems of constituents.

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

7 Section 3. Definitions.

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

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

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

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

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

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

25 Section 4. Research and clinical studies of psilocybin and
26 psilocybin-assisted therapy.

27 The department, in collaboration with the advisory committee,
28 shall contract with at least one academic research institution
29 for the purpose of collecting and studying the efficacy and
30 cost-benefit optimization of psilocybin and psilocybin-assisted

1 therapy in the treatment of mental health conditions and
2 traumatic brain injury as conducted in clinical studies by the
3 academic research institution. The data collected under this
4 section shall include a consideration for individual health
5 outcomes and public health outcomes, including methods to reduce
6 cost and increase scalability of treatment. In conducting the
7 clinical studies for the purposes of this section, the academic
8 research institution shall focus on all of the following
9 conditions:

- 10 (1) Post-traumatic stress disorders.
- 11 (2) Depression.
- 12 (3) Anxiety.
- 13 (4) Suicidal ideation.
- 14 (5) Eating disorders.
- 15 (6) Bipolar disorders.
- 16 (7) Chronic pain.
- 17 (8) Migraines.
- 18 (9) Substance use disorders.
- 19 (10) Traumatic brain injury.
- 20 (11) Any other necessary condition as determined by the
21 department, in collaboration with the advisory committee, or
22 the academic research institution.

23 Section 5. Reports.

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

- 30 (1) The results of the clinical studies of psilocybin

1 conducted by the academic research institution.

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

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

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

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

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

21 (7) Recommendations for legislative actions or other
22 actions for the implementation of a regulatory system
23 governing the use of psilocybin and psilocybin-assisted
24 therapy with the goal of minimizing cost and maximizing the
25 public health benefit of treatment.

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

29 (1) The President pro tempore of the Senate.

30 (2) The Speaker of the House of Representatives.

- 1 (3) The Majority Leader of the Senate.
- 2 (4) The Majority Leader of the House of Representatives.
- 3 (5) The Minority Leader of the Senate.
- 4 (6) The Minority Leader of the House of Representatives.
- 5 (7) The chair and minority chair of the Appropriations
6 Committee of the Senate.
- 7 (8) The chair and minority chair of the Appropriations
8 Committee of the House of Representatives.
- 9 (9) The chair and minority chair of the Health and Human
10 Services Committee of the Senate.
- 11 (10) The chair and minority chair of the Health
12 Committee of the House of Representatives.
- 13 (11) The chair and minority chair of the Human Services
14 Committee of the House of Representatives.
- 15 (12) The chair and minority chair of the Veterans
16 Affairs and Emergency Preparedness Committee of the Senate.
- 17 (13) The chair and minority chair of the Veterans
18 Affairs and Emergency Preparedness Committee of the House of
19 Representatives.
- 20 (c) Confidentiality.--The department shall ensure that
21 protected health data collected from the academic research
22 institution under section 4 remains confidential and does not
23 personally identify an individual in the interim reports and the
24 final report under subsection (a).
- 25 Section 6. Effective date.
- 26 This act shall take effect in 60 days.