

AN ACT

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

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

8 Section 1. Short title.

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

11 Section 2. Declaration of purpose.

12 The General Assembly finds and declares as follows:

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

15 (2) In 2021, more than 47,000,000 Americans were
16 suffering from a mental illness, including more than
17 1,800,000 adults in this Commonwealth, which represents 18%
18 of this Commonwealth's adult population.

19 (3) Of the 1,800,000 adults in this Commonwealth who

1 suffer from a mental illness, more than 727,000 suffered from
2 a substance use disorder and more than 416,000 suffered from
3 serious thoughts of suicide.

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

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

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

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

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

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

27 (10) Similarly, the United States Department of Health
28 and Human Services Centers for Disease Control and Prevention
29 has noted increases in the number of adults seeking mental
30 health care, dealing with anxiety and experiencing symptoms

1 of depressive episodes.

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

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

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

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

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

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

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

30 (18) Additional research is required to determine the

1 efficacy of psilocybin and how to maximize its public health
2 benefits at the lowest cost with the goal of making the
3 treatment broadly available if clinical studies prove
4 successful.

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

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

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

17 Section 3. Definitions.

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

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

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

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

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

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

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

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

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

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

23 Section 4. Research and clinical studies of psilocybin.

24 (a) Evaluation.--The department shall evaluate and determine
25 the efficacy and cost-benefit optimization of psilocybin and
26 psilocybin-assisted therapy in the treatment of mental health
27 conditions and traumatic brain injury as conducted in clinical
28 studies by approved investigators. The department's evaluation
29 under this subsection shall include consideration for individual
30 health outcomes and public health outcomes, including methods to

1 reduce cost and increase scalability of treatment.

2 (b) Clinical studies.--

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

6 (i) Post-traumatic stress disorders.

7 (ii) Depression.

8 (iii) Anxiety.

9 (iv) Suicidal ideation.

10 (v) Eating disorders.

11 (vi) Bipolar disorders.

12 (vii) Chronic pain.

13 (viii) Migraines.

14 (ix) Substance use disorders.

15 (x) Traumatic brain injury.

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

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

22 (i) Therapeutic dose levels.

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

25 (iii) Therapeutic protocols.

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

29 (4) A clinical study of psilocybin conducted under this
30 act may include any of the following:

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

4 (ii) The administration of psilocybin in a
5 supervised group setting. If the administration of
6 psilocybin involves a participant under subparagraph (i),
7 the participant shall be accompanied by a family member
8 who suffers from a condition specified under paragraph
9 (1).

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

12 Section 5. Duties of department.

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

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

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

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

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

28 (5) Adopt standards as the department deems necessary
29 for an entity to be qualified for consideration as an
30 authorized psilocybin manufacturer.

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

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

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

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

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

21 Section 6. Duties of institutional review boards.

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

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

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

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

30 (b) Psilocybin research.--An institutional review board may

1 approve, require modifications in order to secure approval or
2 disapprove psilocybin research.

3 Section 7. Duties of authorized psilocybin manufacturers.

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

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

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

14 Section 8. Duties of approved investigators.

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

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

26 Section 9. Reports.

27 (a) Quarterly reports.--The department shall prepare and
28 submit quarterly reports on the progress of the clinical studies
29 of psilocybin conducted under this act to the Governor, the
30 Lieutenant Governor and each member of the General Assembly.

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

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

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

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

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

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

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

26 (7) Recommendations for legislative actions or other
27 actions for the implementation of a regulatory system
28 governing the use of psilocybin and psilocybin-assisted
29 therapy with the goal of minimizing cost and maximizing the
30 public health benefit of treatment.

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

6 Section 10. Effective date.

7 This act shall take effect in 60 days.