

1 H.859

2 Introduced by Representatives Cina of Burlington, Casey of Montpelier,
3 Headrick of Burlington, Kleppner of Burlington, Logan of
4 Burlington, and McGill of Bridport

5 Referred to Committee on

6 Date:

7 Subject: Health care; human services; mental health; substance use disorder;
8 psychedelic therapy; Psychedelic Therapy Advisory Board; ibogaine;
9 clinical drug development trials

10 Statement of purpose of bill as introduced: This bill proposes to establish a
11 Psychedelic Therapy Advisory Board and requires the Department of Health to
12 enter into a contract with a Vermont entity to perform ibogaine clinical drug
13 development trials.

14 An act relating to psychedelic therapy and clinical drug development trials

15 It is hereby enacted by the General Assembly of the State of Vermont:

16 * * * Psychedelic Therapy Advisory Board* * *

17 Sec. 1. FINDINGS

18 The General Assembly finds that:

19 (1) 2024 Acts and Resolves No. 126, an act relating to the
20 establishment of the Psychedelic Therapy Advisory Working Group, was

1 enacted by the Vermont General Assembly “for the purpose of reviewing
2 existing research on the cost-benefit profile of the use of psychedelics to
3 improve mental health and to make findings and recommendations regarding
4 the advisability of the establishment of a State program to permit health care
5 providers to administer psychedelics in a therapeutic setting and the impact on
6 public health of allowing individuals to legally access psychedelics under State
7 law”;

8 (2) on November 12, 2024, the Psychedelic Therapy Advisory Working
9 Group issued a report recommending the “[extension] of the current [W]orking
10 [G]roup with the expansion of participants to monitor the evolution of research
11 and programs across the country and to facilitate the ability to research
12 psychedelic therapies in Vermont”;

13 (3) the current federal administration has acknowledged the benefits of
14 psychedelic treatments in a clinical setting to treat trauma and mental health
15 conditions and it supports ramping up clinical drug development trials to
16 enable doctors’ prescription of psychedelic medicines soon;

17 (4) according to the Texas Ibogaine Initiative, Texas has approved
18 \$50,000,000.00 in state funding to drug development trials for ibogaine as “a
19 breakthrough treatment for substance use disorder, trauma-related conditions,
20 and traumatic brain injury”; and

1 (5) establishing a Psychedelic Therapy Advisory Board in Vermont is a
2 step toward Americans for Ibogaine’s goal of establishing “the medicalization
3 of ibogaine in the United States—specifically, the successful completion of
4 Phase 3 clinical trials, and ultimately, FDA approval.”

5 Sec. 2. PSYCHEDELIC THERAPY ADVISORY BOARD

6 (a) Creation. There is created the Psychedelic Therapy Advisory Board for
7 the purposes of:

8 (1) reviewing existing research and the cost-benefit profile regarding
9 whether the use of psychedelic therapy improves health and well-being,
10 including mental health and substance use disorders;

11 (2) proposing recommendations regarding the establishment of a State
12 program to permit health care providers to administer psychedelics in a
13 therapeutic setting;

14 (3) providing an updated assessment of the public health impact of
15 allowing individuals to legally access psychedelic medications under State law;

16 and

17 (4) exploring the potential of interstate partnership through research and
18 development of novel treatments.

19 (b) Membership. The Advisory Board shall be composed of the following
20 members:

21 (1) the Secretary of Human Services or designee;

1 (2) the Director of the Office of Professional Regulation or designee;

2 (3) a health care professional licensed or certified in Vermont with
3 specialized training in psychedelic therapy or research, appointed by the
4 Commissioner of Health;

5 (4) an attorney licensed in Vermont with experience practicing in the
6 health care field, appointed by the Chief Justice of the Vermont Supreme
7 Court;

8 (5) a physician licensed in the State with experience in the treatment of
9 trauma, substance use disorders, and other health conditions resistant to
10 existing treatments, appointed by the Vermont Medical Society;

11 (6) a psychologist licensed in the State with experience in the treatment
12 of trauma, substance use disorders, and other conditions resistant to existing
13 treatments, appointed by the President of the Vermont Psychological
14 Association;

15 (7) a social worker licensed in this State with experience in the
16 treatment of trauma, substance use disorders, and other health conditions
17 resistant to existing treatments, appointed by the Vermont chapter of the
18 National Association of Social Workers; and

19 (8) three individuals with lived experience of benefitting from
20 psychedelic therapy, one appointed by the Vermont chapter of the National
21 Alliance on Mental Illness, one appointed by the Vermont Association for

1 Mental Health and Addiction Recovery, and one appointed by the Vermont
2 chapter of Veterans of Foreign Wars.

3 (c) Powers and duties. The Advisory Board shall:

4 (1) review the latest research and evidence of the public health benefits
5 and risks of clinical psychedelic treatment;

6 (2) monitor the laws and programs in other states that have authorized
7 the use of psychedelic medication by health care providers in therapeutic
8 settings and the necessary components and resources for Vermont to pursue a
9 similar practice;

10 (3) consider how Vermont can develop and fund harm reduction training
11 and education for health care professionals and the public regarding the use of
12 psilocybin and other psychedelic medications;

13 (4) propose a pilot project for the use of psilocybin-assisted therapies in
14 end-of-life care or for individuals with serious illnesses, trauma, or mental
15 health or substance use disorders; and

16 (5) participate in a research program to evaluate the medical potential of
17 psychedelic treatments, beginning with the ibogaine initiative in Texas, and
18 propose pathways for moving forward with research and development of novel
19 psychedelic treatments.

1 (d) Assistance. The Advisory Board shall have the administrative,
2 technical, and legal assistance of the Agency of Human Services, in
3 collaboration with the Vermont Psychological Association.

4 (e) Report. On or before January 15, 2027, the Advisory Board shall
5 submit a written report to the House Committees on Health Care and on
6 Human Services and to the Senate Committee on Health and Welfare with its
7 findings and any recommendations for legislative action.

8 (f) Meetings.

9 (1) The Secretary of Human Services or designee shall call the first
10 meeting of the Advisory Board to occur on or before August 15, 2026.

11 (2) The Advisory Board shall select a chair from among its members at
12 the first meeting.

13 (3) A majority of the membership shall constitute a quorum.

14 (4) The Advisory Board shall cease to exist on July 1, 2027.

15 (g) Compensation and reimbursement. Members of the Advisory Board
16 who are not participating in their professional capacities shall be entitled to per
17 diem compensation and reimbursement of expenses as permitted under
18 32 V.S.A. § 1010 for not more than eight meetings. Payments to members of
19 the Advisory Board authorized under this subsection shall be made from
20 monies appropriated to the Agency of Human Services.

1 * * * Ibogaine Clinical Drug Trials * * *

2 Sec. 3. 18 V.S.A. § 14 is added to read:

3 § 14. IBOGAINE CLINICAL DRUG TRIALS

4 (a) The Department of Health shall execute a contract with a Vermont
5 entity to conduct certified clinical drug development trials related to the use of
6 ibogaine for the treatment of opioid use disorder, co-occurring substance use
7 disorder, or any other mental health or neurological conditions for which
8 ibogaine demonstrates efficacy.

9 (b) Prior to entering the contract described in subsection (a) of this section,
10 the Department shall obtain the following information from a proposed
11 Vermont entity:

12 (1) a detailed description of the Vermont entity's strategy for obtaining
13 approval for ibogaine from the U.S. Food and Drug Administration through
14 sanctioned clinical drug development trials, including a detailed clinical drug
15 development trial design;

16 (2) a description of the composition of the drug development clinical
17 trial team and team members' expertise;

18 (3) the Vermont entity's plan to submit an investigational new drug
19 application, if it has not already done so;

20 (4) the Vermont entity's plan to seek a breakthrough therapy designation
21 pursuant to 21 U.S.C. § 356 to expedite the clinical drug development trials;

1 (5) protocols for clinical drug development trial participant recruitment,
2 patient screening criteria, administration, aftercare, and post-acute treatment
3 support; and

4 (6) certification of an existing ibogaine drug development agreement
5 with one or more other states or state-sponsored consortia.

6 (c) Before the Department contracts with a Vermont entity, the Department
7 shall negotiate a contract requiring that the Vermont entity:

8 (1) match the State's investment in ibogaine clinical drug development
9 trials with an equal amount of additional funding and devote this total amount
10 to clinical drug development trials conducted within the State, using in-state
11 facilities and Vermont residents as clinical drug development trial participants;

12 (2) work with mental health professionals who are licensed or certified
13 in Vermont;

14 (3) comply with the reporting requirements in this section;

15 (4) establish a plan to ensure broad and accessible ibogaine treatment
16 access to patients within the State following the approval of ibogaine by the
17 U.S. Food and Drug Administration by diverse means, including:

18 (A) providing priority access to ibogaine treatment to residents of the
19 State;

20 (B) seeking third-party access to ibogaine treatment within the State;

1 (C) developing means of access to ibogaine treatment within the
2 State for uninsured and low-income individuals; and

3 (D) training and credentialing health care professionals within the
4 State to administer ibogaine treatment; and

5 (5) provide a plan recognizing the State's economic interest in the
6 intellectual property generated over the course of the ibogaine clinical drug
7 development trials that shares the proceeds from the intellectual property in a
8 manner proportional to the State's contribution to the total cost of the clinical
9 drug development trials, which shall be deposited into the State's Ibogaine
10 Intellectual Property Special Fund established pursuant to subsection (f) of this
11 section.

12 (d) In negotiating a contract with a Vermont entity, the Department may
13 agree to additional terms that make reasonable deviations from the
14 requirements of this section where it results in a contract that is fair and creates
15 at least substantially equivalent value for the State.

16 (e) For the purposes of this section, intellectual property rights and other
17 economic rights accruing to the State arising from ibogaine clinical drug
18 development trials shall include the following as related to the clinical drug
19 development trials:

20 (1) intellectual property, technology, and inventions;

21 (2) patents, trademarks, and licenses;

1 (3) trade secrets, data, and databases;

2 (4) tools, methods, and processes;

3 (5) treatment models or techniques;

4 (6) administration protocols; and

5 (7) works of authorship.

6 (f) There is created the Ibogaine Intellectual Property Special Fund, a
7 special fund established and managed pursuant to 32 V.S.A. chapter 7,
8 subchapter 5 and administered by the Department. The Ibogaine Intellectual
9 Property Special Fund shall consist of all proceeds from the commercialization
10 of intellectual property created in relation to ibogaine clinical drug
11 development trials conducted pursuant to this section. Expenditures from this
12 Special Fund shall be used only for programs or research benefitting
13 populations that suffer from conditions treatable with ibogaine, including
14 individuals with a traumatic brain injury, opioid use disorder, co-occurring
15 substance use disorder, or other neurological or mental health disorders.

16 (g)(1) Once the Department has entered into a contract with a Vermont
17 entity pursuant to this section, the Vermont entity shall prepare and submit the
18 following to the Department on a quarterly basis until the ibogaine clinical
19 drug development trial is completed or otherwise terminated:

20 (A) a report on the progress of the ibogaine clinical drug
21 development trials conducted pursuant to this section; and

1 (B) a financial status report, including information to verify
2 expenditures of State funds and required matching funds.

3 (2) Annually on or before December, until the ibogaine clinical drug
4 development trials are completed or otherwise terminated, the Department
5 shall submit a written report to the House Committees on Health Care and on
6 Human Services and to the Senate Committee on Health and Welfare
7 describing the progress of the ibogaine clinical drug development trials and
8 their related financial status.

9 (h) A health care professional who prescribes, dispenses, or distributes
10 ibogaine as part of an ibogaine clinical drug development trial authorized in
11 this section shall be immune from civil or criminal liability, unless the health
12 care professional's actions with regard to prescribing, dispensing, or
13 distributing ibogaine constituted recklessness, gross negligence, or intentional
14 misconduct.

15 (i) As used in this section:

16 (1) "Health care professional" means a physician licensed pursuant to 26
17 V.S.A. chapter 23 or 33, a physician assistant licensed to prescribe and
18 dispense prescription drugs pursuant to 26 V.S.A. chapter 31, an advanced
19 practice registered nurse authorized to prescribe and dispense prescription
20 drugs pursuant to 26 V.S.A. chapter 28, or a pharmacist licensed pursuant to 26
21 V.S.A. chapter 36.

1 (2) “Ibogaine” means ibogaine and ibogaine-based therapeutics,
2 including ibogaine analogs.

3 (3) “Vermont entity” means a private-public partnership, for-profit or
4 nonprofit organization, or public benefit corporation located in Vermont that is
5 authorized to conduct drug development trials by the U.S. Food and Drug
6 Administration and that has entered into an ibogaine drug development and
7 manufacturing contract with another state planning to conduct drug
8 development trials to obtain U.S. Food and Drug Administration approval for
9 the use of ibogaine.

10 Sec. 4. APPROPRIATION; IBOGAINES CLINICAL DRUG

11 DEVELOPMENT TRIALS

12 In fiscal year 2025, \$300,000.00 is appropriated from the Opioid Abatement
13 Special Fund established in 18 V.S.A. § 4774 to the Department of Health for
14 the purpose of executing a contract with a Vermont entity to conduct certified
15 clinical drug development trials related to the use of ibogaine for the treatment
16 of opioid use disorder, co-occurring substance use disorder, or any other
17 mental health or neurological conditions for which ibogaine demonstrates
18 efficacy pursuant to 18 V.S.A. § 14.

19 * * * Effective Date * * *

20 Sec. 4. EFFECTIVE DATE

21 This act shall take effect on July 1, 2026.