Veterans PTSD Clinical Research Amendments

2026 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Jennifer Dailey-Provost

Senate Sponsor: Kirk A. Cullimore

LONG TITLE

General Description:

This bill addresses psychedelic-assisted therapy for certain veterans.

Highlighted Provisions:

This bill:

- authorizes the Huntsman Mental Health Institute (Huntsman) to conduct a clinical study on the safety and feasibility of psychedelic-assisted therapy for veterans with treatment-resistant post-traumatic stress disorder;
- permits Huntsman to accept donations to fund the clinical study;
- requires Huntsman to begin the clinical study if legislative appropriations and donations combined are equal to or exceed an amount sufficient to begin the study;
- requires reporting to the Health and Human Services Interim Committee;
- provides a sunset date for the provisions related to the clinical study;
- defines terms; and
- makes technical and conforming changes.

Money Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

AMENDS:

63I-1-226, as last amended by Laws of Utah 2025, Chapters 47, 277 and 366

ENACTS:

26B-7-126, Utah Code Annotated 1953

Be it enacted by the Legislature of the state of Utah:

Section 1. Section **26B-7-126** is enacted to read:

<u>26B-7-126</u> . Psychedelic-assisted therapy for veterans clinical study -- Funding --

H.B. 390

Reports.

(1) As used in this section:

(a) "Clinical study" means the safety and feasibility study authorized in this section.

(b) "Controlled substance" means the same as that term is defined in Section 58-37-2.

(c) "Eligible veteran" means a veteran who has treatment-resistant PTSD.

(d) "FDA" means the United States Food and Drug Administration.

(e) "Huntsman Mental Health Institute" means the mental health and substance use treatment institute within the University of Utah.

(f) "Individualized dose-escalation regimen" means a regimen in which a psychedelic drug is administered under medical supervision in increasing doses according to predefined dose levels, stopping rules, therapeutic response, and clinical judgment.

(g) "Investigational drug" means an investigational new drug that the FDA has authorized for human subjects research under 21 C.F.R. Part 312.

(h) "Investigational new drug" means the same as that term is defined in 21 C.F.R. Sec. 312.3.

(i) "Psychedelic drug" means a controlled substance that is an investigational drug and has a hallucinogenic effect on the central nervous system, including:

(i) 3,4-Methylenedioxymethamphetamine (MDMA);

(ii) 5-methoxy-N,N-dimethyltryptamine;

(iii) Dimethyltryptamine, some trade or other names: DMT;

(iv) Ibogaine, some trade and other names: 7-Ethyl-6,6,7,8,9,10,12,13-octahydro-2-methoxy-6,9-methano-5H-pyrido [1', 2':1,2] azepino [5,4-b] indole; Tabernanthe iboga;

(v) Lysergic acid diethylamide; or

(vi) Psilocybin.

(j) "Psychedelic-assisted therapy" means an intervention where:

(i) a psychedelic drug is administered to an individual with treatment-resistant PTSD:

(A) in a controlled clinical setting; and

(B) when appropriate, under an individualized dose-escalation regimen; and

(ii) a qualified therapist delivers manualized, trauma-informed preparatory and integrative psychotherapy to the individual before and after administration of the psychedelic drug.

(k) "PTSD" means post-traumatic stress disorder.

(l) "Treatment-resistant PTSD" means a clinical diagnosis of PTSD with documented

inadequate response to one or more evidence-based treatments for PTSD.

(2) Subject to Subsections (4) and (5), within appropriations from the Legislature for this purpose and any gifts, grants, or donations the Huntsman Mental Health Institute receives under Subsection (3), the Huntsman Mental Health Institute shall conduct a clinical study to research the safety and feasibility of psychedelic-assisted therapy for the treatment of treatment-resistant PTSD in eligible veterans.

(3) The Huntsman Mental Health Institute may accept gifts, grants, and donations of money to fund the clinical study.

(4)(a) The Huntsman Mental Health Institute shall begin the clinical study no later than January 1, 2027, if the total amount of legislative appropriations and gifts, grants, or donations the Huntsman Mental Health Institute receives under Subsection (3) reaches an amount that is equal to or exceeds an amount the Huntsman Mental Health Institute determines is sufficient to begin the clinical study.

(b) If the Huntsman Mental Health Institute begins the clinical study on or before January 1, 2027, the Huntsman Mental Health Institute may:

(i) accept gifts, grants, or donations after January 1, 2027; and

(ii) use amounts received under Subsection (3), or appropriated by the Legislature for this purpose, after January 1, 2027, to continue funding the clinical study.

(5) If the Huntsman Mental Health Institute does not begin the study on or before January 1, 2027, because the total amounts accepted and appropriated under this section are insufficient to begin the clinical study, the Huntsman Mental Health Institute:

(a) may continue to accept gifts, grants, or donations, after January 1, 2027;

(b) shall begin the clinical study when the total amount of legislative appropriations and gifts, grants, or donations reaches an amount that is equal to or exceeds an amount the Huntsman Mental Health Institute determines is sufficient to begin the clinical study; and

(c) may use amounts received under Subsection (3), or appropriated by the Legislature for this purpose, after January 1, 2027, to continue funding the clinical study.

(6) The Huntsman Mental Health Institute shall return to a donor any unused gifts, grants, or donations the Huntsman Mental Health Institute received under Subsection (3) on or before July 1, 2032.

(7) Before beginning the clinical study, the Huntsman Mental Health Institute shall:

(a) comply with state and federal regulations, including by:

(i) ensuring that the clinical study will be conducted under an FDA investigational

new drug application;

(ii) maintaining a United States Drug Enforcement Agency Schedule I research registration and any required state controlled substance registration; and

(iii) obtaining Institutional Review Board approval for the clinical study;

(b) have a clinical study protocol that includes:

(i) the study design, inclusion and exclusion criteria, objectives and endpoints, eligible veteran visit schedule, and schedule of follow-up assessments;

(ii) informed consent procedures and participant safeguards; and

(iii) data security and privacy protections, including for personal information;

(c) have a drug administration plan for the clinical study that includes:

(i) the investigational drug product description, source, formulation, route of administration, and dosing regimen;

(ii) when appropriate, an individualized dose-escalation regimen, including predefined dose levels, stopping rules, and therapeutic response evaluation criteria;

(iii) a clinical staffing model and monitoring procedures for the administration of the investigational drug;

(iv) discharge criteria and transportation procedures for participants after psychedelic-assisted therapy; and

(v) procedures for the storage, handling, chain of custody, and disposal of controlled substances, and an accountability plan for violations of the procedures;

(d) have a safety monitoring and risk management plan for the clinical study that includes:

(i) medical and psychiatric screening procedures;

(ii) on-site emergency response procedures;

(iii) adverse event and serious adverse event capture and reporting timelines; and

(iv) predefined rules for pausing or stopping the clinical study; and

(e) have a fidelity plan for the clinical study that includes:

(i) a psychotherapy manual that describes preparatory sessions, therapeutic support boundaries for the administration of the investigational drug during psychedelic-assisted therapy sessions, and integrative sessions;

(ii) therapist licensure and qualification requirements;

(iii) a training, supervision, and fidelity monitoring plan; and

(iv) ethical safeguards and a participant complaint and grievance process.

(8)(a) The Huntsman Mental Health Institute shall:

(i) report to the Health and Human Services Interim Committee, upon request of the committee, on the progress of the clinical study; and

(ii) submit a final written report of the clinical study to the Health and Human Services Interim Committee on or before the committee's first November meeting after the date on which the Huntsman Mental Health Institute concludes the clinical study.

(b) The report described in Subsection (8)(a)(ii) shall include:

(i) safety and feasibility outcomes for the use of psychedelic-assisted therapy for the treatment of treatment-resistant PTSD in eligible veterans; and

(ii) secondary or exploratory clinical outcomes of the clinical study.

Section 2. Section **63I-1-226** is amended to read:

63I-1-226 . Repeal dates: Titles 26 through 26B.

(1) Subsection 26B-1-204(2)(g), regarding the Youth Electronic Cigarette, Marijuana, and Other Drug Prevention Committee, is repealed July 1, 2030.

(2) Subsection 26B-1-204(2)(h), regarding the Primary Care Grant Committee, is repealed July 1, 2035.

(3) Section 26B-1-315, Medicaid ACA Fund, is repealed July 1, 2034.

(4) Section 26B-1-318, Brain and Spinal Cord Injury Fund, is repealed July 1, 2029.

(5) Section 26B-1-402, Rare Disease Advisory Council Grant Program -- Creation -- Reporting, is repealed July 1, 2026.

(6) Section 26B-1-409, Utah Digital Health Service Commission -- Creation -- Membership -- Duties, is repealed July 1, 2025.

(7) Section 26B-1-410, Primary Care Grant Committee, is repealed July 1, 2035.

(8) Section 26B-1-417, Brain and Spinal Cord Injury Advisory Committee -- Membership -- Duties, is repealed July 1, 2029.

(9) Section 26B-1-422, Early Childhood Utah Advisory Council -- Creation -- Compensation -- Duties, is repealed July 1, 2029.

(10) Section 26B-1-425, Utah Health Workforce Advisory Council -- Creation and membership, is repealed July 1, 2027.

(11) Section 26B-1-428, Youth Electronic Cigarette, Marijuana, and Other Drug Prevention Committee and Program -- Creation -- Membership -- Duties, is repealed July 1, 2030.

(12) Section 26B-1-430, Coordinating Council for Persons with Disabilities -- Policy regarding services to individuals with disabilities -- Creation -- Membership -- Expenses, is repealed July 1, 2027.

(13) Section 26B-1-432, Newborn Hearing Screening Committee, is repealed July 1, 2026.

(14) Section 26B-2-407, Drinking water quality in child care centers, is repealed July 1, 2027.

(15) Subsection 26B-3-107(9), regarding reimbursement for dental hygienists, is repealed July 1, 2028.

(16) Section 26B-3-136, Children's Health Care Coverage Program, is repealed July 1, 2025.

(17) Section 26B-3-137, Reimbursement for diabetes prevention program, is repealed June 30, 2027.

(18) Subsection 26B-3-213(2)(b), regarding consultation with the Behavioral Health Crisis Response Committee, is repealed December 31, 2026.

(19) Section 26B-3-302, DUR Board -- Creation and membership -- Expenses, is repealed July 1, 2027.

(20) Section 26B-3-303, DUR Board -- Responsibilities, is repealed July 1, 2027.

(21) Section 26B-3-304, Confidentiality of records, is repealed July 1, 2027.

(22) Section 26B-3-305, Drug prior approval program, is repealed July 1, 2027.

(23) Section 26B-3-306, Advisory committees, is repealed July 1, 2027.

(24) Section 26B-3-307, Retrospective and prospective DUR, is repealed July 1, 2027.

(25) Section 26B-3-308, Penalties, is repealed July 1, 2027.

(26) Section 26B-3-309, Immunity, is repealed July 1, 2027.

(27) Title 26B, Chapter 3, Part 5, Inpatient Hospital Assessment, is repealed July 1, 2034.

(28) Title 26B, Chapter 3, Part 6, Medicaid Expansion Hospital Assessment, is repealed July 1, 2034.

(29) Title 26B, Chapter 3, Part 7, Hospital Provider Assessment, is repealed July 1, 2028.

(30) Section 26B-3-910, Alternative eligibility -- Report -- Alternative Eligibility Expendable Revenue Fund, is repealed July 1, 2028.

(31) Section 26B-4-710, Rural residency training program, is repealed July 1, 2025.

(32) Subsection 26B-5-112(1)(b), regarding consultation with the Behavioral Health Crisis Response Committee, is repealed December 31, 2026.

(33) Subsection 26B-5-112(5)(b), regarding consultation with the Behavioral Health Crisis Response Committee, is repealed December 31, 2026.

(34) Section 26B-5-112.5, Mobile Crisis Outreach Team Grant Program, is repealed December 31, 2026.

(35) Section 26B-5-114, Behavioral Health Receiving Center Grant Program, is repealed December 31, 2026.

(36) Section 26B-5-118, Collaborative care grant program, is repealed December 31, 2024.

(37) Section 26B-5-120, Virtual crisis outreach team grant program, is repealed December 31, 2026.

(38) Subsection 26B-5-609(1)(a), regarding the Behavioral Health Crisis Response Committee, is repealed December 31, 2026.

(39) Subsection 26B-5-609(3)(b), regarding the Behavioral Health Crisis Response Committee, is repealed December 31, 2026.

(40) Subsection 26B-5-610(1)(b), regarding the Behavioral Health Crisis Response Committee, is repealed December 31, 2026.

(41) Subsection 26B-5-610(2)(b)(ii), regarding the Behavioral Health Crisis Response Committee, is repealed December 31, 2026.

(42) Section 26B-5-612, Integrated behavioral health care grant programs, is repealed December 31, 2025.

(43) Title 26B, Chapter 5, Part 7, Utah Behavioral Health Commission, is repealed July 1, 2029.

(44) Subsection 26B-5-704(2)(a), regarding the Behavioral Health Crisis Response Committee, is repealed December 31, 2026.

(45) Title 26B, Chapter 5, Part 8, Utah Substance Use and Mental Health Advisory Committee, is repealed January 1, 2033.

(46) Section 26B-7-119, Hepatitis C Outreach Pilot Program, is repealed July 1, 2028.

(47) Section 26B-7-122, Communication Habits to reduce Adolescent Threats Pilot Program, is repealed July 1, 2029.

(48) Section 26B-7-123, Report on CHAT campaign, is repealed July 1, 2029.

(49) Section 26B-7-126, Psychedelic-assisted therapy for veterans clinical study -- Funding -- Reports, is repealed July 1, 2032.

[~~(49)~~] (50) Title 26B, Chapter 8, Part 5, Utah Health Data Authority, is repealed July 1, 2026.

Section 3. **Effective Date.**

This bill takes effect on May 6, 2026.