THE SENATE
THIRTY-THIRD LEGISLATURE, 2026
STATE OF HAWAII

S.B. NO. 3199 S.D. 1

A BILL FOR AN ACT

RELATING TO MENTAL HEALTH.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

SECTION 1. The legislature finds that addressing the mental health crisis affecting the residents of the State, particularly among veterans, first responders, and trauma survivors, is urgent. Suicide continues to be a leading cause of preventable death, and the State must explore all safe and effective treatment options supported by scientific evidence.

The legislature furthers finds that the United States Food and Drug Administration has granted breakthrough therapy designation to several emerging treatments, including 3,4-methylenedioxymethamphetamine (MDMA)-assisted therapy for post-traumatic stress disorder and psilocybin-assisted therapy for treatment-resistant depression, in recognition of their potential to provide significant improvements over existing interventions. As federal rescheduling and approval of these therapies are anticipated, the State must proactively prepare public health, clinical, and research systems for safe and equitable implementation.

The legislature also finds that several states, including New Mexico, Texas, Oregon, and Connecticut, have already taken meaningful steps toward establishing frameworks for clinical research, pilot programs, or medical access pathways for emerging mental health therapies. Without similar action, Hawaii risks falling behind and limiting access for residents and communities most affected by trauma.

Accordingly, the purpose of this Act is to establish a two-year mental health emerging therapies task force within an entity with demonstrated expertise in primary scientific research and pharmaceutical or medical education, charged with preparing the State for the integration of federally rescheduled breakthrough therapies, expanding pathways for clinical trials and clinical research in the State, and developing policy recommendations for safe, ethical, and culturally-informed implementation.

SECTION 2. (a) There is established the mental health emerging therapies task force within an entity with demonstrated expertise in primary scientific research and pharmaceutical or medical education.

(b) The task force shall consist of the following thirteen members:

(1) One member representing the Thompson school of social work and public health at the university of Hawaii at Manoa with demonstrated history and expertise in breakthrough and emerging therapies for therapeutic applications, who shall serve as the chair of the taskforce;

(2) One member representing the department of health's alcohol and drug abuse division;

(3) One member representing the department of health's adult mental health division;

(4) One member representing the department of the attorney general;

(5) One member representing the office of wellness and resilience;

(6) One member representing the John A. Burns school of medicine at the university of Hawaii at Manoa; and

(7) Seven members to be invited by the chair, comprising:

(A) One member representing a veteran-serving institution;

(B) One member representing a Native Hawaiian health organization;

(C) One member representing an expert in controlled-substances laws and regulations;

(D) Two licensed psychiatrists or psychologists with expertise in trauma and post-traumatic stress disorder; and

(E) Two community members with lived experience as veterans, first responders, or family caregivers.

The chair may invite any other stakeholder the chair deems appropriate to participate in the task force.

(c) The task force shall:

(1) Prepare the State for federal rescheduling and medical approval of 3,4-methylenedioxymethamphetamine (MDMA), psilocybin, and other drugs or treatments designated as breakthrough therapies by the United States Food and Drug Administration;

(2) Identify opportunities and requirements for expanding local clinical trials, investigator-initiated research, and university-based research partnerships;

(3) Develop educational partnerships to help expand awareness of clinical research opportunities for potential beneficiaries of breakthrough therapies;

(4) Recommend training, certification, and workforce development pathways for licensed professionals who may administer or support emerging therapies;

(5) Evaluate best practices from other jurisdictions regarding patient safety, culturally-informed care, equity, access, and harm reduction;

(6) Develop a statewide implementation roadmap for integrating emerging therapies pending federal approval; and

(7) Make legislative, administrative, and other recommendations to support long-term adoption of mental health emerging therapies in the State.

(d) An entity with demonstrated expertise in primary scientific research and pharmaceutical or medical education shall provide administrative, technical, and research support to the task force.

(e) Administrative placement of the task force within an entity with demonstrated expertise in primary scientific

research and pharmaceutical or medical education shall not be construed to transfer, delegate, diminish, expand, or otherwise modify any regulatory, enforcement, licensing, scheduling, or rulemaking authority vested in the department of health, the board of pharmacy, or any other state agency. All statutory authority relating to controlled substances, professional licensure, and public health regulation shall remain with the appropriate executive branch agencies as provided by law.

(f) The task force may form working groups, invite subject matter experts, and contract with third-party organizations to carry out its duties under this section.

(g) Members of the task force shall serve without compensation but may be reimbursed for reasonable expenses, including travel expenses, necessary for their duties.

(h) The task force shall submit to the legislature:

(1) An interim report of its findings and recommendations, including any proposed legislation, no later than twenty days prior to the convening of the regular session of 2027; and

(2) A final report of its findings and recommendations, including any proposed legislation, no later than

twenty days prior to the convening of the regular session of 2028.

(i) For the purposes of this section:

"Breakthrough therapy" means any drug or treatment that has received breakthrough therapy designation by the United States Food and Drug Administration for a mental health or behavioral health condition.

"Clinical trial" means any phase II or phase III trials regulated by the United States Food and Drug Administration, investigator-initiated trials, or state-authorized research studies designed to evaluate safety, efficacy, treatment delivery, or implementation models.

"Emerging therapy" means therapy using any psychedelic or entactogenic compound therapy that:

(1) Is undergoing clinical trials regulated by the United States Food and Drug Administration;

(2) Has been approved for marketing by the United States Food and Drug Administration; or

(3) Has been rescheduled or authorized for medical use under state law.

"Psychedelic" means a substance that produces altered states of consciousness with potential therapeutic benefit, including psilocybin, MDMA, and ibogaine.

SECTION 3. If any drug or treatment designated as a breakthrough therapy by the United States Food and Drug Administration is scheduled, rescheduled, or descheduled as a controlled substance under federal law, the board of pharmacy shall similarly control, reschedule, or deschedule the drug or treatment in accordance with section 329-11, Hawaii Revised Statutes, within ninety days after publication of the applicable notice in the Federal Register or interim final order.

SECTION 4. This Act shall take effect on January 30, 2050, and shall be repealed on June 30, 2028.

S.B. NO. 3199 S.D. 1

Report Title:
Mental Health; Emerging Therapies; Task Force; Reports

Description:
Establishes the Mental Health Emerging Therapies Task Force to prepare the State for the integration of breakthrough therapies, expansion of pathways for clinical trials and clinical research, and development of policy recommendations for safe, ethical, and culturally informed implementation of emerging therapies. Requires reports to the Legislature. Sunsets 6/30/2028. Effective 1/30/2050. (SD1)

The summary description of legislation appearing on this page is for informational purposes only and is not legislation or evidence of legislative intent.