THE SENATE
THIRTY-THIRD LEGISLATURE, 2025
STATE OF HAWAII

S.B. NO. 1042

JAN 17 2025

A BILL FOR AN ACT

RELATING TO MENTAL HEALTH.

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

SECTION 1. Chapter 321, Hawaii Revised Statutes, is amended by adding a new section to part I to be appropriately designated and to read as follows:

"**§321- Mental health emerging therapies special fund.** (a) There is established in the state treasury the mental health emerging therapies special fund to be administered by the department of health. The following moneys shall be deposited into the fund:

(1) Appropriations by the legislature to the special fund; and

(2) Gifts, donations, and grants from public agencies and private persons.

All interest earned or accrued on moneys deposited into the special fund shall become part of the special fund.

(b) Moneys in the special fund shall be expended to support clinical research and the development of emerging therapies for the treatment of mental health and behavioral

health disorders. Among other purposes, the moneys may be used for:

(1) Establishing public-private partnerships to jointly fund phase three clinical trials of United States Food and Drug Administration breakthrough therapies;

(2) Funding investor-initiated clinical trials, including trials to:

(A) Inform optimal methods of treatment delivery; and

(B) Inform transdiagnostic safety and efficacy;

(3) Establishing compassionate use programs, including data collection and analysis;

(4) Funding education and training opportunities for mental health professionals;

(5) Supporting public education and harm reduction;

(6) Developing patient access pilot programs, including real-world data collection and analysis;

(7) Establishing community programs to provide long-term patient support services; and

(8) Funding implementation studies, including research and analyses of best practices, cost effectiveness, and methods to reduce treatment costs.

(c) The department shall adopt rules pursuant to chapter 91 for the administration of the mental health emerging therapies special fund.

(d) The department shall submit to the legislature no later than twenty days prior to the convening of each regular session, beginning with the regular session of 2026, a report of:

(1) The studies funded and efforts supported by the mental health emerging therapies special fund in the previous year;

(2) The department's findings and recommendations; and

(3) Any proposed legislation.

(e) For the purposes of this section:

"Compassionate use" means treating patients suffering from terminal or life-threatening conditions, including treatment-resistant mental health conditions under either the federal Right to Try Act (P.L. 115-176) or the Food and Drug Administration Expanded Access program (21 United States Code section 360bbb(b)).

"Emerging therapies" means any psychedelic or entactogenic compound or mixture that is either:

(1) Undergoing clinical trials regulated by the United States Food and Drug Administration for the treatment of a mental or behavioral health condition;

(2) Approved by the United States Food and Drug Administration for marketing in interstate commerce; or

(3) Approved for medical use under Hawaii law.

"United States Food and Drug Administration breakthrough therapies" means investigational drugs that have been granted breakthrough therapy designation by the United States Food and Drug Administration under section 506(a) of the Food, Drug, and Cosmetic Act (21 United States Code section 356(a))."

SECTION 2. There is appropriated out of the general revenues of the State of Hawaii the sum of $ or so much thereof as may be necessary for fiscal year 2025-2026 and the same sum or so much thereof as may be necessary for fiscal year 2026-2027 for deposit into the mental health emerging therapies special fund.

SECTION 3. There is appropriated out of the mental health emerging therapies special fund the sum of $ or so much thereof as may be necessary for fiscal year 2025-2026 and the

same sum or so much thereof as may be necessary for fiscal year 2026-2027 for supporting clinical research and the use of emerging therapies for treating mental and behavioral health disorders.

The sums appropriated shall be expended by the department of health for the purposes of this Act.

SECTION 4. New statutory material is underscored.

SECTION 5. This Act shall take effect on July 1, 2025.

INTRODUCED BY: _____

S.B. NO. 1042

Report Title:
DHS; Mental Health; Emerging Therapies, Breakthrough Therapies; Special Fund; Reports; Appropriation

Description:
Establishes and appropriates moneys for a mental health emerging therapies special fund, to be administered by the Department of Health. Requires annual reports to the Legislature.

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