

JAN 17 2025

A BILL FOR AN ACT

RELATING TO MENTAL HEALTH.

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

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

4 "§321- Mental health emerging therapies special fund.

5 (a) There is established in the state treasury the mental
6 health emerging therapies special fund to be administered by the
7 department of health. The following moneys shall be deposited
8 into the fund:

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

10 and

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

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

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



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

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

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

8 (A) Inform optimal methods of treatment delivery; and

9 (B) Inform transdiagnostic safety and efficacy;

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

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

14 (5) Supporting public education and harm reduction;

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

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

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



1 (c) The department shall adopt rules pursuant to chapter
2 91 for the administration of the mental health emerging
3 therapies special fund.

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

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

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

12 (3) Any proposed legislation.

13 (e) For the purposes of this section:

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

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



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(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



1 same sum or so much thereof as may be necessary for fiscal year
2 2026-2027 for supporting clinical research and the use of
3 emerging therapies for treating mental and behavioral health
4 disorders.

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

7 SECTION 4. New statutory material is underscored.

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

9

INTRODUCED BY:

A handwritten signature in black ink, appearing to be 'C. W.', is written over a horizontal line.

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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.

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

