

JAN 17 2025

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# 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        (1) Undergoing clinical trials regulated by the United
- 2                States Food and Drug Administration for the treatment
- 3                of a mental or behavioral health condition;
- 4        (2) Approved by the United States Food and Drug
- 5                Administration for marketing in interstate commerce;
- 6                or
- 7        (3) Approved for medical use under Hawaii law.

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

13        SECTION 2. There is appropriated out of the general  
14 revenues of the State of Hawaii the sum of \$                or so much  
15 thereof as may be necessary for fiscal year 2025-2026 and the  
16 same sum or so much thereof as may be necessary for fiscal year  
17 2026-2027 for deposit into the mental health emerging therapies  
18 special fund.

19        SECTION 3. There is appropriated out of the mental health  
20 emerging therapies special fund the sum of \$                or so much  
21 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.

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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.*

