HOUSE OF REPRESENTATIVES
THIRTY-SECOND LEGISLATURE, 2023
STATE OF HAWAII

H.B. NO. 1340 H.D. 2 S.D. 2

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 mental health conditions are treated in various ways, depending on the condition, and that treatments may include medication, therapy, or psychosocial services. Congress, through the Breakthrough Therapies Act, and the United States Food and Drug Administration, have indicated that 3,4-methylenedioxymethamphetamine, commonly known as MDMA, and psilocybin have the potential to be rescheduled for therapeutic use. MDMA and psilocybin have already been granted the Food and Drug Administration's breakthrough therapy designation to fast-track research and potential approval, given the drugs' efficacy for treating treatment-resistant depression and post-traumatic stress disorder. These treatments, while effective for certain conditions and patients, do not treat all mental health conditions. However, research supports the use of natural and alternative medicines and therapies, including MDMA, psilocybin, and other therapies, as safe and effective ways to

potentially treat depression, post-traumatic stress disorder, addiction, end-of-life psychological distress, and other afflictions.

The legislature further finds that the department of health should be empowered to evaluate applicable laws, regulations, and studies each time a breakthrough therapy designation is issued to review any new treatment intended for mental health or substance abuse and to prepare the State for the treatment's potential approval by the United States Food and Drug Administration.

Accordingly, the purpose of this Act is to require the director of health to establish a temporary breakthrough therapy designation advisory council to evaluate potential new treatments within three months of certain breakthrough therapy designation approvals by the United States Food and Drug Administration.

SECTION 2. 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- Temporary breakthrough therapy designation advisory council.** (a) The director of health shall establish a

temporary breakthrough therapy designation advisory council to evaluate potential new treatments for a mental health condition or substance abuse disorder within three months of the United States Food and Drug Administration's approval of a designated breakthrough therapy. The advisory council shall be established within the department of health for administrative purposes only.

(b) The advisory council shall comprise the following members or their designees:

(1) The executive director of the office of wellness and resilience, who shall serve as the chairperson of the advisory council;

(2) The attorney general;

(3) The director of law enforcement;

(4) The chairpersons of the standing committees within the senate and house of representatives with primary jurisdiction over health;

(5) A physician who is duly licensed pursuant to chapter 453, or an advanced practice registered nurse who is authorized to prescribe psychotropic medication and is

duly licensed pursuant to chapter 457, who shall be invited by the chairperson to participate; and

(6) Other members as recommended by the director of health, president of the senate, or speaker of the house of representatives, and invited to participate by the chairperson, representing applicable community, advocacy, or stakeholder interests.

(c) Members shall serve without compensation, but may be reimbursed for necessary expenses, including reasonable travel expenses, incurred in the performance of their duties.

(d) The advisory council shall:

(1) Examine federal and state laws, regulations, administrative rules, and community practices regarding the treatment of mental health conditions or substance abuse disorders to which the breakthrough therapy designation applies;

(2) Examine available clinical and scientific studies, research, and other information relating to the safety and efficacy of methods to treat mental health conditions or substance abuse disorders to which the breakthrough therapy designation applies;

(3) Examine any requirements, specifications, and guidelines for health care professionals who prescribe and provide various treatments for patients who may benefit; and

(4) Submit a report of its findings and recommendations, including any proposed legislation, to the legislature no later than one year after the advisory council is convened.

(e) The advisory council may convene as necessary but shall terminate upon the withdrawal of the breakthrough therapy designation or the treatment's final approval by the United States Food and Drug Administration.

(f) As used in this section, "breakthrough therapy designation" or "designated breakthrough therapy" means a designation by the United States Food and Drug Administration, pursuant to the Food and Drug Administration Safety and Innovation Act (P.L. 112-144)."

SECTION 3. New statutory material is underscored.

SECTION 4. This Act shall take effect upon its approval.

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Report Title:
Temporary Breakthrough Therapy Designation Advisory Council; Department of Health; Mental Health

Description:
Requires the Director of Health to establish a Temporary Breakthrough Therapy Designation Advisory Council within 3 months of certain breakthrough therapy designation approvals by the United States Food and Drug Administration. (SD2)

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