

STAND. COM. REP. NO.

1404

Honolulu, Hawaii

MAR 24 2023

RE: H.B. No. 1340  
H.D. 2  
S.D. 1

Honorable Ronald D. Kouchi  
President of the Senate  
Thirty-Second State Legislature  
Regular Session of 2023  
State of Hawaii

Sir:

Your Committee on Health and Human Services, to which was referred H.B. No. 1340, H.D. 2, entitled:

"A BILL FOR AN ACT RELATING TO MENTAL HEALTH,"

begs leave to report as follows:

The purpose and intent of this measure is to authorize the Director of Health to establish a Temporary Breakthrough Therapy Designation Advisory Council within three months of a breakthrough therapy designation approval by the United States Food and Drug Administration.

Your Committee received testimony in support of this measure from the Department of Health, Clarity Project, Heroic Hearts Project, Hawai'i Psychological Association, SoundMind Institute, Beyond Mental Health, and twenty-seven individuals.

Your Committee finds that the United States Food and Drug Administration grants certain "breakthrough therapy" designations to expedite research and potential approval for drugs that treat a serious condition and whose preliminary clinical evidence indicates a substantial improvement over other available therapies. Although the post-breakthrough approval process can sometimes take four to six years following designation, your Committee believes that by concurrently reviewing the applicable scientific, legal, and regulatory background for each new therapy,



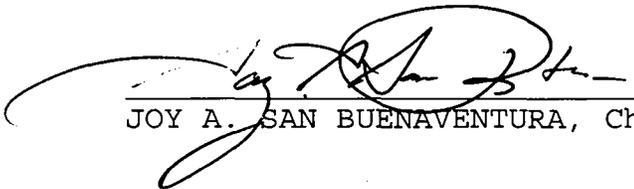
the State will be better prepared to more quickly implement new breakthrough therapies once they receive federal approval. Further, your Committee believes that this improved process will also help expedite already-designated breakthrough therapies that are nearing federal approval, such as MDMA and psilocybin, which are proving to be promising therapies for a wide range of mental and psychiatric diagnosis. Therefore, this measure allows the Director of Health to convene a Temporary Breakthrough Therapy Designation Advisory Council for each new breakthrough therapy and to review any new treatment to help get life-changing therapies to the people of Hawaii faster and more efficiently.

Your Committee has amended this measure by:

- (1) Designating the Executive Director of the Office of Wellness and Resilience as the Chairperson of any established Temporary Breakthrough Therapy Designation Advisory Council, rather than the Director of Health;
- (2) Making it effective upon its approval; and
- (3) Making technical, nonsubstantive amendments for the purposes of clarity and consistency.

As affirmed by the record of votes of the members of your Committee on Health and Human Services that is attached to this report, your Committee is in accord with the intent and purpose of H.B. No. 1340, H.D. 2, as amended herein, and recommends that it pass Second Reading in the form attached hereto as H.B. No. 1340, H.D. 2, S.D. 1, and be referred to your Committee on Ways and Means.

Respectfully submitted on  
behalf of the members of the  
Committee on Health and Human  
Services,



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JOY A. SAN BUENAVENTURA, Chair



The Senate  
 Thirty-Second Legislature  
 State of Hawai'i

**Record of Votes**  
**Committee on Health and Human Services**  
**HHS**

Bill / Resolution No.:*	Committee Referral:	Date:
<i>HB 1340 HD2</i>	<i>HHS, LAM</i>	<i>3/22/23</i>
<input type="checkbox"/> The Committee is reconsidering its previous decision on this measure. If so, then the previous decision was to: _____		
The Recommendation is:		
<input type="checkbox"/> Pass, unamended 2312	<input checked="" type="checkbox"/> Pass, with amendments 2311	<input type="checkbox"/> Hold 2310
<input type="checkbox"/> Recommit 2313		
Members	Aye	Aye (WR)
Nay	Excused	
SAN BUENAVENTURA, Joy A. (C)	✓	
AQUINO, Henry J.C. (VC)	✓	
MORIWAKI, Sharon Y.	✓	
SHIMABUKURO, Maile S.L.	✓	
AWA, Brenton	✓	<i>GA GA</i>
<b>TOTAL</b>	<i>5 GA HA</i>	<i>GA HA</i>
Recommendation:		
<input checked="" type="checkbox"/> Adopted <span style="margin-left: 200px;"><input type="checkbox"/> Not Adopted</span>		
Chair's or Designee's Signature: <i>[Signature]</i>		
Distribution:		
Original File with Committee Report	Yellow Clerk's Office	Pink Drafting Agency
Goldenrod Committee File Copy		

\*Only one measure per Record of Votes