

The House Committee on Public and Community Health offers the following substitute to HB 1296:

A BILL TO BE ENTITLED  
AN ACT

1 To amend Article 1 of Chapter 1 of Title 37 of the Official Code of Georgia Annotated,  
2 relating to general provisions for governing and regulation of mental health, so as to provide  
3 for a pilot program to support clinical research of certain eligible breakthrough treatments  
4 and provide such treatments to certain veterans and first responders suffering from certain  
5 conditions; to provide for definitions; to provide for funding and use of funds; to provide for  
6 eligibility; to provide for an annual report; to provide for rules and regulations; to provide  
7 for termination and automatic repeal; to provide for related matters; to provide for contingent  
8 effectiveness upon appropriation of funds; to repeal conflicting laws; and for other purposes.

9 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

10 **SECTION 1.**

11 Article 1 of Chapter 1 of Title 37 of the Official Code of Georgia Annotated, relating to  
12 general provisions for governing and regulation of mental health, is amended by adding a  
13 new Code section to read as follows:

14 "37-1-8.

15 (a) As used in this Code section, the term:

16 (1) 'Eligible breakthrough treatment' means:

H. B. 1296 (SUB)

- 17 (A) Any medical device that has been granted breakthrough device designation by the  
18 United States Food and Drug Administration in effect on or after January 1, 2026;  
19 (B) Any approved or investigational drug that has been granted breakthrough therapy  
20 designation by the United States Food and Drug Administration in effect on or after  
21 January 1, 2026;  
22 (C) Ibogaine or an ibogaine based therapeutic, including analogs;  
23 (D) Transcranial magnetic stimulation, including investigational or approved  
24 accelerated transcranial magnetic stimulation protocols; or  
25 (E) Any other investigational or approved device or drug as determined by the  
26 department; provided, however, that such investigational or approved device or drug  
27 is substantially similar to a treatment described in this paragraph.
- 28 (2) 'First responder' shall have the same meaning as set forth in Code Section 26-4-116.2.  
29 (3) 'Program' means the Breakthrough Treatments for Georgia Heroes Suicide Prevention  
30 Pilot Program developed by this Code section.
- 31 (4) 'Veteran' shall have the same meaning as set forth in Code Section 50-5-131.
- 32 (b) Beginning on January 1, 2027, subject to appropriations, the department shall develop,  
33 implement, and conduct a three-year pilot program to support clinical research and provide  
34 eligible breakthrough treatment to veterans and retired first responders suffering from  
35 post-traumatic stress disorder, treatment-resistant depression, major depressive disorder,  
36 traumatic brain injury, or other related conditions as determined in rules and regulations  
37 established by the department. Such program shall be known as the Breakthrough  
38 Treatments for Georgia Heroes Suicide Prevention Pilot Program.
- 39 (c) Consistent with the program's purpose as described in subsection (b) of this Code  
40 section, program funds may, without limitation, be used to:
- 41 (1) Establish a network of approved program sites in diverse geographic regions and  
42 treatment settings with required standardized data collection, sharing, and analysis across  
43 such sites;

- 44 (2) Conduct clinical research and implement studies of eligible breakthrough treatments,  
45 including, but not limited to:
- 46 (A) Clinical trials of any breakthrough treatment for a relevant condition to support the  
47 approval of any such treatment by the United States Food and Drug Administration;  
48 (B) Clinical trials or real-world studies to inform optimal treatment delivery methods  
49 that improve scalability and cost effectiveness;  
50 (C) Comparative effectiveness trials; and  
51 (D) Cost effectiveness analyses of approved breakthrough treatments and protocols  
52 approved by the United States Food and Drug Administration;
- 53 (3) Subsidize the cost of eligible breakthrough treatments at approved program sites;  
54 (4) Invest in clinical infrastructure, to include without limitation, facility, equipment, and  
55 data collection system costs for approved program sites in underserved areas;  
56 (5) Provide healthcare workforce education and training at approved program sites; and  
57 (6) Establish and disseminate treatment guidelines for eligible breakthrough treatments.
- 58 (d) The department is authorized to enter into partnerships, memoranda of understanding,  
59 or contracts with public and private postsecondary research institutions accredited by the  
60 Southern Association of Colleges and Schools Commission on Colleges in the State of  
61 Georgia to facilitate the implementation and operation of the program.
- 62 (e) The department may apply for, receive, administer, and use any grant, other financial  
63 assistance, or other funds made available to the department from any government or other  
64 source for furthering the purposes of the program.
- 65 (f) The department shall provide an annual report by December 31 to the Governor, the  
66 President of the Senate, the Speaker of the House of Representatives, the chairpersons of  
67 the House Committee on Health and the Senate Health and Human Services Committee,  
68 and the chairpersons of the House Committee on Defense and Veterans Affairs and the  
69 Senate Veterans, Military, and Homeland Security Committee. Such report shall include,

70 at a minimum, detailed information on the implementation and effectiveness of the  
71 program.

72 (g) The department is authorized to promulgate rules and regulations as may be necessary  
73 to carry out and implement the provisions of this Code section.

74 (h) The program developed by this Code section shall terminate on January 1, 2030, and  
75 this Code section shall be repealed by operation of law on such date."

76 **SECTION 2.**

77 (a) This Act shall become effective only if funds are specifically appropriated for purposes  
78 of this Act in an appropriations Act enacted by the General Assembly.

79 (b) If funds are so appropriated, then this Act shall become effective on the later of:

80 (1) The date on which such appropriations becomes effective; or

81 (2) The beginning date of the fiscal year for which such appropriations are made.

82 **SECTION 3.**

83 All laws and parts of laws in conflict with this Act are repealed.