

Senate Bill 631

By: Senators Halpern of the 39th, Anderson of the 43rd, Wicks of the 34th, Jackson of the 41st and Parent of the 44th

A BILL TO BE ENTITLED

AN ACT

1 To amend Article 1 of Chapter 2A Title 31 of the Official Code of Georgia Annotated,  
2 relating to general provisions of the Department of Public Health, so as to authorize the  
3 department to award grants to eligible entities to conduct clinical trials approved by the  
4 United States Food and Drug Administration as a part of a multistate consortium using  
5 ibogaine as an investigational new drug for the treatment of opioid use disorder, co-occurring  
6 substance use disorder, and any other neurological or mental health conditions as related to  
7 veterans for which ibogaine demonstrates efficacy; to provide for waiver; to provide for  
8 definitions; to provide for revenue attributable to intellectual property rights and other  
9 commercial rights relative to clinical trials; to provide for the awarding of grants by the  
10 Department of Public Health; to provide for certain eligibility requirements; to provide for  
11 certain verifications; to provide for certain limitations on disbursement; to provide for  
12 reporting; to provide for construction; to provide for related matters; to provide for a short  
13 title; to provide for an effective date; to provide for contingencies; to repeal conflicting laws;  
14 and for other purposes.

15 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

S. B. 631

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16

**SECTION 1.**

17 This Act shall be known and may be cited as the "Veterans Mental Health Innovations Act."

18

**SECTION 2.**

19 Article 1 of Chapter 2A Title 31 of the Official Code of Georgia Annotated, relating to  
20 general provisions of the Department of Public Health, is amended by adding a new Code  
21 section to read as follows:

22 "31-2A-21.

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

24 (1) 'Armed forces' means the United States army, navy, marine corps, space force, coast  
25 guard, air force, Georgia National Guard, or other reserve unit of the United States  
26 military.

27 (2) 'Clinical trial' means a clinical trial program approved by the federal Food and Drug  
28 Administration and conducted in this state as part of a multistate consortium for the  
29 investigational use of ibogaine for the treatment of opioid use disorder, co-occurring  
30 substance use disorder, and any other neurological or mental health conditions as related  
31 to veterans for which ibogaine demonstrates efficacy.

32 (3) 'Ibogaine' means ibogaine and ibogaine based therapeutics, including ibogaine  
33 analogs.

34 (4) 'Multistate consortium' means a collection of state, research institutions or state  
35 agencies from different states collaborating or associating for the purpose of conducting  
36 clinical trials concerning the medicinal use of ibogaine.

37 (5) 'Veteran' means a former member of the armed forces who received an honorable  
38 discharge.

39 (b) Subject to appropriations by the General Assembly for such purpose, the department  
40 shall be authorized to award grants to entities to participate in clinical trials, provided that  
41 the department has obtained a waiver or authorization from the federal government if such

42 department determines that such waiver or authorization is required under federal law for  
43 the implementation of any provision of this Code section. The department shall only award  
44 a grant pursuant to this Code section to an applicant that:

45 (1) Is located within this state;

46 (2) Has a history of proven research and treatment of neurological conditions and  
47 expertise in substance dependence and emotional, physical or neurological trauma as  
48 related to veterans;

49 (3) Has a neurosurgery program with clinical and research facilities authorized to enter  
50 into a multistate consortium agreement and is:

51 (A) Staffed by professionals with expertise in neurological and neurosurgical  
52 conditions; and

53 (B) Capable of providing the necessary infrastructure and expertise to deliver cardiac  
54 intensive care services;

55 (4) Has the ability to facilitate research and innovation in the diagnosis and treatment of  
56 neurological conditions as related to veterans;

57 (5) Has demonstrated to the department that the entity has the financial capability to  
58 match moneys from gifts, grants, and donations from sources other than this state in the  
59 amount of at least \$7 million to conduct the clinical trials described in this Code section;  
60 and

61 (6) Has agreed to enter into an agreement with a multistate consortium by which the  
62 applicant or an agent or joint venture thereof has agreed to:

63 (A) Submit an investigational new drug application to the United States Food and Drug  
64 Administration in accordance with 21 C.F.R. Part 312; and

65 (B) Request a breakthrough therapy designation for ibogaine from the United States  
66 Food and Drug Administration under 21 U.S.C. Section 356.

67 (c) An applicant selected to conduct clinical trials shall quarterly, prepare and submit to the  
68 department:

- 69 (1) A report on the progress of the clinical trials conducted under this Code section; and  
70 (2) A financial status report, including information verifying expenditures of state funds  
71 and required matching funds.
- 72 (d) All revenue attributable to all intellectual property rights and other commercial rights  
73 that may arise from the clinical trials conducted by the entity receiving the grant described  
74 in subsection (b) of this Code section during the period for which trials are funded shall be  
75 deposited into the state general fund. For purposes of this subsection, intellectual property  
76 rights and other commercial rights arising from the clinical trials conducted under this  
77 Code section shall include any of the following as related to such trials:
- 78 (1) Intellectual property, technology, and inventions;  
79 (2) Patents, trademarks, and licenses;  
80 (3) Proprietary and confidential information;  
81 (4) Trade secrets, data, and databases;  
82 (5) Tools, methods, and processes;  
83 (6) Treatment models or techniques;  
84 (7) Administration protocols; and  
85 (8) Works of authorship.
- 86 (e) The commissioner shall prepare an accounting of the funds expended pursuant to this  
87 Code section during the most recently completed fiscal year to be reported to the Office of  
88 Planning and Budget, the House Budget and Research Office, and the Senate Budget and  
89 Evaluation Office by January 1 of each year.
- 90 (f) The department shall submit to the General Assembly a report on the progress of the  
91 clinical trials and their related financial status conducted under this Code section not later  
92 than December 1 of each year. Such report shall include information verifying  
93 expenditures of state funds and required matching funds.
- 94 (g) Nothing in this Code section shall be construed to preclude a physician from  
95 administering ibogaine in accordance with federal law and state law."

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**SECTION 3.**

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

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

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

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

102 (c) If funds are not appropriated by July 1, 2029, as described in this section, this Act shall  
103 stand repealed.

104

**SECTION 4.**

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