

AN ACT

relating to the establishment of a consortium to conduct United States Food and Drug Administration's drug development clinical trials with ibogaine to secure the administration's approval of the medication's use for treatment of opioid use disorder, co-occurring substance use disorder, and any other neurological or mental health conditions for which ibogaine demonstrates efficacy and to the administration of that treatment.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Subtitle C, Title 6, Health and Safety Code, is amended by adding Chapter 491 to read as follows:

CHAPTER 491. IBOGAINE TREATMENT

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 491.001. DEFINITIONS. In this chapter:

(1) "Commission" means the Health and Human Services Commission.

(2) "Comptroller" means the comptroller of public accounts.

(3) "Drug developer" means a pharmaceutical company, biotechnology company, or contract development and manufacturing organization engaged in drug development and manufacturing.

(4) "Hospital" has the meaning assigned by Section [241.003](#).

(5) "Ibogaine" means ibogaine and ibogaine-based

therapeutics, including ibogaine analogs.

(6) "Institution of higher education" has the meaning assigned by Section 61.003, Education Code.

SUBCHAPTER B. DRUG DEVELOPMENT OF IBOGAINE TREATMENT

Sec. 491.051. ESTABLISHMENT OF CONSORTIUM. (a) A consortium may be established under this section and apply for commission selection under this subchapter to conduct drug development clinical trials with ibogaine and secure the United States Food and Drug Administration's approval of ibogaine as a medication for the treatment of:

- (1) opioid use disorder;
- (2) co-occurring substance use disorder; and
- (3) any other neurological or mental health condition for which ibogaine demonstrates efficacy.

(b) A consortium established under this section must include one or more of each of the following entities:

- (1) a drug developer;
- (2) an institution of higher education; and
- (3) a hospital.

Sec. 491.052. LEAD INSTITUTION; ADMINISTRATION; PERSONNEL.

(a) A consortium established under this subchapter shall select a lead institution of higher education from among the consortium's members to represent the consortium and perform administrative functions under this subchapter, including contracting with and reporting to the commission as required by this subchapter.

(b) A consortium selected by the commission under this subchapter may employ personnel, including clinical,

1 administrative, and data management personnel, necessary to  
2 support any consortium member's activities related to drug  
3 development clinical trials conducted under this subchapter.

4 Sec. 491.053. CONSORTIUM PROPOSAL. (a) The lead  
5 institution of higher education of a consortium shall submit to the  
6 commission a proposal and request for funding on behalf of the  
7 consortium for purposes of conducting ibogaine drug development  
8 clinical trials in accordance with this subchapter.

9 (b) A proposal submitted under Subsection (a) must provide:

10 (1) the identity of all consortium members;

11 (2) a detailed description of the planned strategy for  
12 obtaining approval for the drug development clinical trials from  
13 the United States Food and Drug Administration;

14 (3) a detailed drug development clinical trial design  
15 that includes:

16 (A) a description of the composition of the  
17 consortium's drug development clinical trial team and the expertise  
18 of the team members;

19 (B) a drug development clinical trial  
20 participant recruitment plan;

21 (C) patient screening criteria and cardiac  
22 safety protocols;

23 (D) administration protocols;

24 (E) an aftercare and post-acute treatment  
25 support plan; and

26 (F) a data integrity plan;

27 (4) a detailed plan to seek a breakthrough therapy

1 designation for ibogaine from the United States Food and Drug  
2 Administration under 21 U.S.C. Section 356;

3 (5) a proposal to recognize this state's commercial  
4 interest in all intellectual property that may be generated over  
5 the course of the drug development clinical trials, including:

6 (A) the treatment that is the subject of the  
7 trials;

8 (B) administration protocols;

9 (C) treatment models or techniques; and

10 (D) technology used in the trials;

11 (6) a plan to establish a corporate presence in this  
12 state and to promote and maintain ibogaine-related biomedical  
13 research, development, treatment, manufacturing, and distribution  
14 in this state;

15 (7) a plan to secure third-party payor approval for  
16 ibogaine treatment following approval by the United States Food and  
17 Drug Administration through:

18 (A) private insurers;

19 (B) Medicare;

20 (C) Medicaid; and

21 (D) the TRICARE program of the United States  
22 Department of Defense;

23 (8) a plan to ensure ibogaine treatment access to  
24 uninsured individuals following approval by the United States Food  
25 and Drug Administration;

26 (9) a plan to train and credential medical providers  
27 to administer ibogaine treatment according to developed clinical

1 standards; and

2 (10) financial disclosures that verify the  
3 consortium's capacity to fully match state funding with funds  
4 received from non-state sources.

5 Sec. 491.054. COMMISSION SELECTION. The commission, in the  
6 commission's sole discretion, shall select a consortium  
7 established in accordance with Section 491.051 for the purpose of  
8 conducting ibogaine drug development clinical trials under this  
9 subchapter.

10 Sec. 491.055. CONTRACT WITH LEAD INSTITUTION. (a) As soon  
11 as practicable after selecting a consortium to conduct ibogaine  
12 drug development clinical trials under Section 491.054, the  
13 commission shall enter into an interagency contract, as provided by  
14 Chapter 771, Government Code, with the lead institution of higher  
15 education of the selected consortium to provide funding to  
16 implement the consortium's proposed ibogaine drug development  
17 clinical trials.

18 (b) The interagency contract described by Subsection (a)  
19 must specify:

20 (1) the goals and objectives of the proposed ibogaine  
21 drug development clinical trials;

22 (2) the proposed budget;

23 (3) the timeline for completing the proposed  
24 objectives;

25 (4) the for-profit, nonprofit, or public benefit  
26 corporate entities collaborating with the consortium in the drug  
27 development clinical trials under this subchapter;

1           (5) the percentage of the revenue arising from the  
2 drug development clinical trials to be paid to the state; and

3           (6) any other information required by the commission.

4           (c) As soon as practicable after entering into an  
5 interagency contract under Subsection (a), the commission shall  
6 report the existence of the contract to the legislature.

7           (d) The commission may not disburse funds to or for a  
8 selected consortium under the interagency contract described by  
9 Subsection (a) until the consortium receives and the commission  
10 verifies the receipt of matching funds from sources other than the  
11 state.

12           Sec. 491.056. INVESTIGATIONAL NEW DRUG APPLICATION. On the  
13 commission's notification that a consortium is selected to conduct  
14 the drug development clinical trials under this subchapter, a drug  
15 developer or hospital member of the selected consortium or the lead  
16 institution of higher education of the consortium, as specified by  
17 written agreement of the consortium members, shall, as soon as  
18 practicable:

19           (1) submit an investigational new drug (IND)  
20 application to the United States Food and Drug Administration in  
21 accordance with 21 C.F.R. Part 312; and

22           (2) seek a breakthrough therapy designation for  
23 ibogaine from the United States Food and Drug Administration under  
24 21 U.S.C. Section 356.

25           Sec. 491.057. DRUG DEVELOPMENT CLINICAL TRIAL SITES. For  
26 purposes of conducting a drug development clinical trial under this  
27 subchapter, only an institution of higher education or a hospital

1 may serve as a trial site.

2 Sec. 491.058. FUNDING; DISBURSEMENT BY COMMISSION. (a)  
3 The commission and consortium members may solicit and accept gifts,  
4 grants, and donations of any kind received from sources other than  
5 the state for purposes of funding drug development clinical trials  
6 under this subchapter.

7 (b) Disbursements of funds by the commission may be made  
8 incrementally based on the completion of clearly defined objectives  
9 as negotiated in the contract described by Section 491.055,  
10 including verifiable documentation demonstrating the efficient  
11 expenditure of both state and matching funds.

12 Sec. 491.059. REPORTING REQUIREMENTS. (a) A consortium  
13 selected to conduct ibogaine drug development clinical trials shall  
14 quarterly prepare and submit to the commission:

15 (1) a report on the progress of the drug development  
16 clinical trials conducted under this subchapter; and

17 (2) a financial status report, including information  
18 to verify expenditures of state funds and required matching funds.

19 (b) The commission shall submit a report to the legislature  
20 on the progress of the drug development clinical trials conducted  
21 under this subchapter not later than December 1 of each year.

22 Sec. 491.060. ALLOCATION OF REVENUE ATTRIBUTABLE TO  
23 INTELLECTUAL PROPERTY AND OTHER RIGHTS. (a) The revenue  
24 attributable to all intellectual property rights and other  
25 commercial rights arising from drug development clinical trials  
26 conducted by a consortium under this subchapter during the period  
27 for which the trials are funded and any following period of

commercialization shall be allocated as follows:

(1) not less than 20 percent to the state as specified in the contract under Section 491.055; and

(2) the remainder to the members of the consortium in the amounts specified by written agreement of the members.

(b) For purposes of this section, intellectual property rights and other commercial rights arising from the drug development clinical trials conducted under this subchapter include any of the following as related to the trials:

(1) intellectual property, technology, and inventions;

(2) patents, trademarks, and licenses;

(3) proprietary and confidential information;

(4) trade secrets, data, and databases;

(5) tools, methods, and processes;

(6) treatment models or techniques;

(7) administration protocols; and

(8) works of authorship.

Sec. 491.061. USE OF STATE REVENUE. (a) The comptroller shall deposit the revenue received under Section 491.060 to the credit of the general revenue fund.

(b) Of the amount deposited under Subsection (a), 25 percent may be appropriated only to programs that assist veterans in this state.

(c) The comptroller shall develop accounting procedures for the purpose of implementing this section.



1           SUBCHAPTER C. IBOGAINЕ TREATMENT ADMINISTRATION

2           Sec. 491.101. APPLICABILITY. This subchapter applies only  
3 if ibogaine is approved by the United States Food and Drug  
4 Administration to treat a medical condition.

5           Sec. 491.102. MEDICAL SUPERVISION. A physician licensed  
6 under Subtitle B, Title 3, Occupations Code, who has prescribed  
7 ibogaine for a patient shall supervise the administration of  
8 ibogaine at a hospital or other licensed health care facility to  
9 ensure the patient's safety while the patient is under the  
10 influence of ibogaine.

11           Sec. 491.103. ADMINISTRATION UNDER FEDERAL LAW. This  
12 subchapter does not preclude a physician from administering  
13 ibogaine in accordance with federal law.

14           SECTION 2. (a) If before implementing any provision of this  
15 Act a state agency determines that a waiver or authorization from a  
16 federal agency is necessary for implementation of that provision,  
17 the agency affected by the provision shall request the waiver or  
18 authorization and may delay implementing that provision until the  
19 waiver or authorization is granted.

20           (b) The Health and Human Services Commission shall begin  
21 accepting proposals from consortiums under Chapter 491, Health and  
22 Safety Code, as added by this Act, not later than the 60th day after  
23 the effective date of this Act.

24           SECTION 3. This Act takes effect immediately if it receives  
25 a vote of two-thirds of all the members elected to each house, as  
26 provided by Section 39, Article III, Texas Constitution. If this  
27 Act does not receive the vote necessary for immediate effect, this

S.B. No. 2308

1 Act takes effect September 1, 2025.

<hr style="border: none; border-top: 1px solid black; margin-bottom: 5px;"/> <div>President of the Senate</div>	<hr style="border: none; border-top: 1px solid black; margin-bottom: 5px;"/> <div>Speaker of the House</div>
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I hereby certify that S.B. No. 2308 passed the Senate on April 30, 2025, by the following vote: Yeas 26, Nays 5; May 15, 2025, Senate refused to concur in House amendments and requested appointment of Conference Committee; May 20, 2025, House granted request of the Senate; May 31, 2025, Senate adopted Conference Committee Report by the following vote: Yeas 27, Nays 4.

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Secretary of the Senate

I hereby certify that S.B. No. 2308 passed the House, with amendments, on May 13, 2025, by the following vote: Yeas 138, Nays 2, two present not voting; May 20, 2025, House granted request of the Senate for appointment of Conference Committee; June 1, 2025, House adopted Conference Committee Report by the following vote: Yeas 134, Nays 4, one present not voting.

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Chief Clerk of the House

Approved:

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Date

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Governor

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