

HEALTH AND SAFETY CODE

TITLE 6. FOOD, DRUGS, ALCOHOL, AND HAZARDOUS SUBSTANCES

SUBTITLE C. SUBSTANCE ABUSE REGULATION AND CRIMES

Chapter 491, consisting of Secs. 491.001 to 491.103, was added by Acts 2025, 89th Leg., R.S., Ch. 333 (S.B. [2308](#)), Sec. 1.

For another Chapter 491, consisting of Secs. 491.001 to 491.151, added by Acts 2025, 89th Leg., R.S., Ch. 285 (S.B. [984](#)), Sec. 1, see Sec. 491.001 et seq., post.

For another Chapter 491, consisting of Secs. 491.001 to 491.151, added by Acts 2025, 89th Leg., R.S., Ch. 352 (S.B. [670](#)), Sec. 2, see Sec. 491.001 et seq., post.

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.

Added by Acts 2025, 89th Leg., R.S., Ch. 333 (S.B. [2308](#)), Sec. 1, eff. June 11, 2025.

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.

Added by Acts 2025, 89th Leg., R.S., Ch. 333 (S.B. [2308](#)), Sec. 1, eff. June 11, 2025.

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

Added by Acts 2025, 89th Leg., R.S., Ch. 333 (S.B. [2308](#)), Sec. 1, eff. June 11, 2025.

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

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

- (1) the identity of all consortium members;
- (2) a detailed description of the planned strategy for

obtaining approval for the drug development clinical trials from the United States Food and Drug Administration;

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

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

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

(C) patient screening criteria and cardiac safety protocols;

(D) administration protocols;

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

(F) a data integrity plan;

(4) a detailed plan to seek a breakthrough therapy designation for ibogaine from the United States Food and Drug Administration under 21 U.S.C. Section 356;

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

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

(B) administration protocols;

(C) treatment models or techniques; and

(D) technology used in the trials;

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

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

(A) private insurers;

(B) Medicare;

(C) Medicaid; and

(D) the TRICARE program of the United States

Department of Defense;

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

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

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

Added by Acts 2025, 89th Leg., R.S., Ch. 333 (S.B. 2308), Sec. 1, eff. June 11, 2025.

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

Added by Acts 2025, 89th Leg., R.S., Ch. 333 (S.B. 2308), Sec. 1, eff. June 11, 2025.

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

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

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

(2) the proposed budget;

(3) the timeline for completing the proposed objectives;

(4) the for-profit, nonprofit, or public benefit

corporate entities collaborating with the consortium in the drug development clinical trials under this subchapter;

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

(6) any other information required by the commission.

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

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

Added by Acts 2025, 89th Leg., R.S., Ch. 333 (S.B. [2308](#)), Sec. 1, eff. June 11, 2025.

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

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

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

Added by Acts 2025, 89th Leg., R.S., Ch. 333 (S.B. [2308](#)), Sec. 1, eff. June 11, 2025.

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

Added by Acts 2025, 89th Leg., R.S., Ch. 333 (S.B. [2308](#)), Sec. 1,

eff. June 11, 2025.

Sec. 491.058. FUNDING; DISBURSEMENT BY COMMISSION.

(a) The commission and consortium members may solicit and accept gifts, grants, and donations of any kind received from sources other than the state for purposes of funding drug development clinical trials under this subchapter.

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

Added by Acts 2025, 89th Leg., R.S., Ch. 333 (S.B. [2308](#)), Sec. 1, eff. June 11, 2025.

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

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

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

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

Added by Acts 2025, 89th Leg., R.S., Ch. 333 (S.B. [2308](#)), Sec. 1, eff. June 11, 2025.

Sec. 491.060. ALLOCATION OF REVENUE ATTRIBUTABLE TO INTELLECTUAL PROPERTY AND OTHER RIGHTS. (a) The revenue attributable to all intellectual property rights and other commercial rights arising from drug development clinical trials conducted by a consortium under this subchapter during the period 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.

Added by Acts 2025, 89th Leg., R.S., Ch. 333 (S.B. 2308), Sec. 1, eff. June 11, 2025.

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.

Added by Acts 2025, 89th Leg., R.S., Ch. 333 (S.B. 2308), Sec. 1, eff. June 11, 2025.

SUBCHAPTER C. IBOGAINE TREATMENT ADMINISTRATION

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

Added by Acts 2025, 89th Leg., R.S., Ch. 333 (S.B. 2308), Sec. 1, eff. June 11, 2025.

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

Added by Acts 2025, 89th Leg., R.S., Ch. 333 (S.B. [2308](#)), Sec. 1, eff. June 11, 2025.

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

Added by Acts 2025, 89th Leg., R.S., Ch. 333 (S.B. [2308](#)), Sec. 1, eff. June 11, 2025.