By: Parker S.B. No. 2308

A BILL TO BE ENTITLED

AN ACT

relating to the establishment of a grant program to fund the United States Food and Drug Administration's drug development trials with ibogaine for the purpose of securing the administration's approval as a medication 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 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. GRANT PROGRAM FOR DRUG DEVELOPMENT OF IBOGAINE TREATMENT

Sec. 491.001. DEFINITIONS. In this chapter:

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

(2) "Executive commissioner" means the executive commissioner of the Health and Human Services Commission.

Sec. 491.002. RULES. The executive commissioner shall adopt rules necessary to administer this chapter.

Sec. 491.003. ESTABLISHMENT OF GRANT PROGRAM. The commission shall establish and administer a grant program to fund a public-private partnership program that will pay for the costs of

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

Sec. 491.004. APPLICATION. (a) The commission shall prepare and issue a notice of funding opportunity to solicit applications for the grant program established under this subchapter.

(b) An applicant may apply to the commission in the form and manner prescribed by the commission for a grant under this subchapter. To be eligible for a grant, an applicant must:

(1) be a for-profit, nonprofit, or public benefit corporate entity that has the requisite organizational and financial capacity to:

(A) conduct the United States Food and Drug Administration's drug development trials with ibogaine to secure the administration's approval as a medication for treatment of opioid use disorder, co-occurring substance use disorder, and any other neurological or mental health conditions for which ibogaine demonstrates efficacy;

(B) as a result of the data obtained from the drug development trial described by Paragraph (A), seek United States Food and Drug Administration approval of ibogaine; and

(C) conduct future drug development trials of ibogaine as a medication 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

(2) provide:

(A) a detailed description of the planned strategy for obtaining approval for the drug development trial from the United States Food and Drug Administration;

(B) a detailed drug development trial design that includes:

(i) a description of the composition of the applicant's drug development trial team and the expertise of the team members;

(ii) a drug development trial participant recruitment plan;

(iii) detailed patient screening criteria and cardiac safety protocols;

(iv) administration protocols;

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

(vi) a data integrity plan;

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

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

(ii) administration protocols;

(iii) treatment models or techniques; and

(iv) technology used in the trials;

(D) 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;

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

(i) private insurers;

(ii) Medicare;

(iii) Medicaid; and

(iv) the TRICARE program of the United States Department of Defense;

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

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

(H) financial disclosures that verify the applicant's capacity to fully match state funding.

(c) The commission shall:

(1) make available the application required under this section; and

(2) announce a period of not less than 90 days during which applicants may submit an application under this subchapter.

Sec. 491.005. SELECTION COMMITTEE. (a) The commission

shall create a selection committee and select the number of members. The committee must be composed of:

(1) subject matter experts;

(2) philanthropic partners; and

(3) legislative designees.

(b) The selection committee shall review applications, communicate supplemental inquiries to applicants, and recommend to the commission the best applicants to conduct the drug development trials.

(c) The commission shall consider the recommendations of the selection committee in selecting the applicant to conduct the ibogaine drug development trial.

Sec. 491.006. INVESTIGATIONAL NEW DRUG APPLICATION. On notification from the commission that the applicant was selected to conduct the ibogaine drug development trial, the applicant shall, as soon as practicable:

(1) submit an investigational new drug (IND) application with 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.

Sec. 491.007. ESTABLISHMENT OF DRUG DEVELOPMENT TRIAL SITES. On approval of the applicant's investigational new drug application by the United States Food and Drug Administration, the commission shall, in consultation with the applicant, establish drug development trial sites that must be equipped and staffed to

provide cardiac intensive care services to patients.

Sec. 491.008. CONDUCTING DRUG DEVELOPMENT TRIAL. (a) As soon as practicable after drug development trial sites are established under Section 491.007, the applicant shall begin a drug development trial to administer treatment with ibogaine.

(b) The commission, in consultation with the selection committee under Section 491.005, shall select an institutional review board with a presence in this state to oversee and verify the drug development trial research activity for scientific validation and authentication under the requirements of the United States Food and Drug Administration.

(c) The applicant shall request the designation under 21 U.S.C. Section 356 during the drug development trial if the ibogaine treatment is demonstrating efficacy.

Sec. 491.009. FUNDING. (a) The commission may use money received as a gift, grant, or donation to pay for a grant under this subchapter. The commission may solicit and accept gifts, grants, and donations of any kind and from any source for purposes of this section.

(b) An applicant selected to perform a drug development trial under this subchapter shall contribute toward the cost of developing the ibogaine treatment an amount of money that is at least equal to the amount of money that the applicant received in the form of a grant from the commission.

SUBCHAPTER B. IBOGAINE TREATMENT ADMINISTRATION

Sec. 491.051. APPLICABILITY. This subchapter applies only if ibogaine is approved by the United States Food and Drug

Administration to treat a medical condition.

Sec. 491.052. 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.

Sec. 491.053. ADMINISTRATION UNDER FEDERAL LAW PERMITTED. This subchapter does not preclude a physician from otherwise administering ibogaine according to federal law.

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

SECTION 3. This Act takes effect immediately if it receives a vote of two-thirds of all the members elected to each house, as provided by Section 39, Article III, Texas Constitution. If this Act does not receive the vote necessary for immediate effect, this Act takes effect September 1, 2025.