

## **BILL ANALYSIS**

C.S.S.B. 2308  
By: Parker  
Public Health  
Committee Report (Substituted)

### **BACKGROUND AND PURPOSE**

The bill sponsor has informed the committee that opioid use disorder (OUD) continues to be one of the most insidious threats to public health of our time, devastating individuals, families, and communities across Texas and our nation, and that current treatment options are often unsuccessful in treating OUD and lives are lost as a result. As reported by NBC News, ibogaine, a naturally occurring psychoactive compound, has shown incredible promise in early research as an effective and fast-acting treatment for OUD and other related or co-occurring conditions. However, ibogaine must undergo costly FDA-approved clinical trials before it can become a viable treatment option. C.S.S.B. 2308 seeks to enable Texas to take a leading role in advancing a breakthrough treatment for OUD and other mental health conditions and save lives in the process by requiring the Health and Human Services Commission to establish and administer a grant program to fund a public-private partnership program that will pay for the costs of the FDA's drug development trials with ibogaine to secure FDA approval as a medication for treatment of OUD, co-occurring substance use disorder, and any other neurological or mental health conditions for which ibogaine demonstrates efficacy.

### **CRIMINAL JUSTICE IMPACT**

It is the committee's opinion that this bill does not expressly create a criminal offense, increase the punishment for an existing criminal offense or category of offenses, or change the eligibility of a person for community supervision, parole, or mandatory supervision.

### **RULEMAKING AUTHORITY**

It is the committee's opinion that rulemaking authority is expressly granted to the executive commissioner of the Health and Human Services Commission in SECTION 1 of this bill.

### **ANALYSIS**

C.S.S.B. 2308 amends the Health and Safety Code to require the Health and Human Services Commission (HHSC) to establish and administer a grant program to fund a public-private partnership program that will pay for the costs of the FDA's drug development trials with ibogaine to secure the FDA'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. The bill requires the executive commissioner of HHSC to adopt rules necessary to administer the bill's provisions.

C.S.S.B. 2308 requires HHSC to prepare and issue a notice of funding opportunity to solicit applications for the grant program and authorizes an applicant to apply to HHSC in the form and manner prescribed by HHSC for a grant. The bill requires an applicant, to be eligible for a grant, to be a for-profit, nonprofit, or public benefit corporate entity that has the requisite organizational and financial capacity to do the following:

- conduct the FDA's drug development trials with ibogaine to secure approval as a medication for treatment of the specified conditions;

- as a result of the data obtained from the drug development trial, seek FDA approval of ibogaine;
- conduct future drug development trials of ibogaine as a medication for such treatment; and
- provide the following:
  - a detailed description of the planned strategy for obtaining approval for the drug development trial from the FDA;
  - a detailed drug development trial design that includes:
    - a description of the composition of the applicant's drug development trial team and the expertise of the team members;
    - a drug development trial participant recruitment plan;
    - detailed patient screening criteria and cardiac safety protocols;
    - FDA protocols;
    - an aftercare and post-acute treatment support plan; and
    - a data integrity plan;
  - a proposal to recognize the state's commercial interest in all patentable intellectual property that may be generated over the course of the drug development trials, including the treatment that is the subject of the trials, FDA protocols, treatment models or techniques, and technology used in the trials;
  - a plan to establish a corporate presence in Texas and to promote and maintain ibogaine-related biomedical research, development, treatment, manufacturing, and distribution in Texas;
  - a plan to secure third-party payor approval for ibogaine treatment following approval by the FDA through private insurers, Medicare, Medicaid, and the TRICARE program of the U.S. Department of Defense;
  - a plan to ensure ibogaine treatment access to uninsured individuals following approval by the FDA;
  - a plan to train and credential medical providers to administer ibogaine treatment according to developed clinical standards; and
  - financial disclosures that verify the applicant's capacity to fully match state funding.

The bill requires HHSC to make the application required under the grant program available and announce a period of not less than 90 days during which applicants may submit an application.

C.S.S.B. 2308 requires HHSC to create a selection committee that must be composed of subject matter experts, philanthropic partners, and legislative designees and to select the number of members. The bill requires the selection committee to review applications, communicate supplemental inquiries to applicants, and recommend to HHSC the best applicants to conduct the drug development trials. The bill requires HHSC to consider the recommendations of the selection committee in selecting the applicant to conduct the trial.

C.S.S.B. 2308 requires an applicant, on notification from HHSC that the applicant was selected to conduct the trial, to submit an investigational new drug (IND) application with the FDA in accordance with federal regulations and to seek a breakthrough therapy designation for ibogaine from the FDA under federal law relating to the expedited approval of drugs for serious or life-threatening diseases or conditions. The bill requires HHSC, on the FDA's approval of the applicant's IND application, to establish, in consultation with the applicant, drug development trial sites that must be equipped and staffed to provide cardiac intensive care services to patients.

C.S.S.B. 2308 requires the applicant, as soon as practicable after drug development trial sites are established, to begin a drug development trial to administer treatment with ibogaine. The bill requires HHSC, in consultation with the selection committee, to select an institutional review board with a presence in Texas to oversee and verify the drug development trial research activity for scientific validation and authentication under the requirements of the FDA. The bill requires the applicant to request a breakthrough therapy designation under federal law during the drug development trial if the ibogaine treatment is demonstrating efficacy.

C.S.S.B. 2308 authorizes HHSC to use money appropriated to HHSC and money received as a gift, grant, or donation to pay for a grant under the bill's provisions. The bill authorizes HHSC to solicit and accept gifts, grants, and donations of any kind and from any source for grant program funding purposes. The bill requires an applicant selected to perform a drug development trial under the grant program to 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 HHSC.

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

### **EFFECTIVE DATE**

On passage, or, if the bill does not receive the necessary vote, September 1, 2025.

### **COMPARISON OF SENATE ENGROSSED AND SUBSTITUTE**

While C.S.S.B. 2308 may differ from the engrossed in minor or nonsubstantive ways, the following summarizes the substantial differences between the engrossed and committee substitute versions of the bill.

While both the engrossed and the substitute authorize HHSC to use money received as a gift, grant, or donation to pay for a grant under the bill's provisions, the substitute also authorizes HHSC to use money appropriated to HHSC to pay for such a grant, whereas the engrossed did not.

The substitute omits the following provisions from the engrossed relating to the administration of ibogaine treatment:

- a provision establishing that the bill's provisions apply only if ibogaine is approved by the FDA to treat a medical condition;
- a requirement for a state-licensed physician who has prescribed ibogaine for a patient to 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; and
- a provision establishing that the bill's provisions do not preclude a physician from otherwise administering ibogaine according to federal law.