LEGISLATIVE BUDGET BOARD Austin, Texas

FISCAL NOTE, 89TH LEGISLATIVE REGULAR SESSION

April 6, 2025

TO: Honorable Gary VanDeaver, Chair, House Committee on Public Health

FROM: Jerry McGinty, Director, Legislative Budget Board

IN RE: HB3717 by Harris (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.), **As Introduced**

The fiscal implications of the bill cannot be determined due to the unknown cost related to the grant funding needs required to conduct the drug development trials.

The bill would 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 United States Food and Drug Administration's (USDA) drug development trials with ibogaine to secure USDA'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. HHSC shall create a selection committee to review and recommend grant applicants. HHSC, in consultation with the selected applicant, shall establish drug development trial sites that must be equipped and staffed to provide cardiac intensive care services to patients. HHSC shall select an Institutional Review Board to oversee and verify the drug development trial research activity. HHSC may use money appropriated for this purpose and gifts, grants, and donations to establish and administer the program. The selected applicant shall contribute toward the cost of developing the ibogaine treatment at an amount of funding that is at least equal to the amount of the grant provided by HHSC.

The cost estimate does not include HHSC's component of the grant funding required to conduct the drug development trials. HHSC would require appropriations to implement the grant program, which are expected to be significant, but the cost for grant funding is unknown at this time as HHSC does not have experience with establishing drug trials and there is no existing program comparable at HHSC to develop a cost estimate for this purpose. Other potential costs are noted below for illustrative purposes.

Based on information provided by HHSC, this analysis assumes HHSC would require additional funding related to technical and scientific support of the drug development trials, including: start-up fees, Institutional Review Board fees, radiological and scanning expenses, and indirect costs. This analysis assumes HHSC would require \$965,309 in General Revenue in fiscal year 2026 and \$965,309 in General Revenue in fiscal year 2027 for related technical and scientific support services.

This analysis assumes HHSC would require an additional 3.0 full-time-equivalents (FTEs) to implement other provisions of the bill, including: 1.0 Contract Specialist V for procurement- and contract-related activities, 1.0 Budget Analyst IV for budget management oversight and assistance, and 1.0 Psychiatrist IV to serve as a psychiatric clinical director and direct and supervise clinical aspects of the drug development trials. Personnel-related costs, including salaries and travel for select FTEs, are estimated to total \$749,760 in General Revenue in fiscal year 2026 and \$721,512 in General Revenue in fiscal year 2027.

The bill establishes a matching grant program at HHSC. This analysis assumes HHSC would require an estimated \$10,000 in General Revenue per fiscal year to track the grant in the Grant Management System.

Local Government Impact

No significant fiscal implication to units of local government is anticipated.

Source Agencies: 529 Health and Human Services Commission

LBB Staff: JMc, NPe, ER, SB, NV