WEST VIRGINIA LEGISLATURE

2026 REGULAR SESSION

Introduced

House Bill 4626

FISCAL NOTE

By Delegates Browning, Worrell, Burkhammer, Dean,

Heckert, Hillenbrand, and Hite

[Introduced January 21, 2026; referred to the

Committee on Health and Human Resources]

A BILL to amend the Code of West Virginia, 1931, as amended, by adding a new article, designated §16-67-1, §16-67-2, §16-67-3, §16-67-4, §16-67-5, §16-67-6, and §16-67-7, relating to the establishment of a grant program to fund the United States Food and Drug Administration’s drug development trials with ibogaine; the preparation and notice of funding opportunity; application requirements; the creation of a selection committee; the submission of an investigational new drug application with the United States Food and Drug Administration; requesting a breakthrough therapy designation for ibogaine from the United States Food and Drug Administration; the establishment of drug development trial sites; conducting drug development trials; the selection of an institutional review board; and funding.

Be it enacted by the Legislature of West Virginia:

ARTICLE 67. GRANT PROGRAM FOR DRUG DEVELOPMENT OF IBOGAINE TREATMENT.

§16-67-1. Establishment of Grant Program.

The Secretary of Health 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.

§16-67-2. Application.

(a) The secretary shall prepare and issue a notice of funding opportunity to solicit applications for the grant program established under this chapter.

(b) An applicant may apply to the secretary in the form and manner prescribed by the Secretary for a grant under this chapter. 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 secretary 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 section.

§16-67-3. Selection Committee.

(a) The secretary 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 secretary the best applicants to conduct the drug development trials.

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

§16-67-4. Investigational New Drug Application.

On notification from the secretary 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.

§16-67-5. 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 secretary 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.

§16-67-6. Conducting Drug Development Trial.

(a) As soon as practicable after drug development trial sites are established under §16-67-5 of this code, the applicant shall begin a drug development trial to administer treatment with ibogaine.

(b) The secretary, in consultation with the selection committee under §16-67-3 of this code, 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. §356 during the drug development trial if the ibogaine treatment is demonstrating efficacy.

§16-67-7. Funding.

(a) The secretary may use money appropriated to the secretary and money received as a gift, grant, or donation to pay for a grant under this chapter. The secretary 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 chapter 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 secretary.

NOTE: The purpose of this bill is to establish 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.

Strike-throughs indicate language that would be stricken from a heading or the present law and underscoring indicates new language that would be added.