

WEST VIRGINIA LEGISLATURE

2025 REGULAR SESSION

ENGROSSED

House Bill 3344

By Delegates Worrell, Hite, Burkhammer, and

Browning

[Introduced March 13, 2025; referred to the
Committee on Health and Human Resources]

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

Be it enacted by the Legislature of West Virginia:

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

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

1 The Secretary of Health shall establish and administer a grant program to fund a public-
2 private partnership program that will pay for the costs of the United States Food and Drug
3 Administration's drug development trials with ibogaine to secure the administration's approval as a
4 medication for treatment of opioid use disorder, co-occurring substance use disorder, and any
5 other neurological or mental health conditions for which ibogaine demonstrates efficacy.

§16-67-2. Application.

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

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

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

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

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

13 (C) Conduct future drug development trials of ibogaine as a medication for treatment of
14 opioid use disorder, co-occurring substance use disorder, and any other neurological or mental
15 health conditions for which ibogaine demonstrates efficacy; and

16 (2) Provide:

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

19 (B) A detailed drug development trial design that includes:

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

22 (ii) A drug development trial participant recruitment plan;

23 (iii) Detailed patient screening criteria and cardiac safety protocols;

24 (iv) Administration protocols;

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

26 (vi) A data integrity plan;

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

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

30 (ii) Administration protocols;

31 (iii) Treatment models or techniques; and

32 (iv) Technology used in the trials;

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

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

38 (i) Private insurers;

39 (ii) Medicare;

40 (iii) Medicaid; and

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

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

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

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

47 (c) The Secretary shall:

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

49 (2) Announce a period of not less than 90 days during which applicants may submit an
50 application under this section.

§16-67-3. Selection Committee.

1 (a) The Secretary shall create a selection committee and select the number of members.

2 The committee must be composed of:

3 (1) Subject matter experts;

4 (2) Philanthropic partners; and

5 (3) Legislative designees.

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

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

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

1 On notification from the Secretary that the applicant was selected to conduct the ibogaine
2 drug development trial, the applicant shall, as soon as practicable:

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

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

§16-67-5. Establishment of Drug Development Trial Sites.

1 On approval of the applicant's investigational new drug application by the United States
2 Food and Drug Administration, the Secretary shall, in consultation with the applicant, establish
3 drug development trial sites that must be equipped and staffed to provide cardiac intensive care
4 services to patients.

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

1 (a) As soon as practicable after drug development trial sites are established under §16-67-
2 5 of this code, the applicant shall begin a drug development trial to administer treatment with
3 ibogaine.

4 (b) The Secretary, in consultation with the selection committee under §16-67-3 of this
5 code, shall select an institutional review board with a presence in this state to oversee and verify
6 the drug development trial research activity for scientific validation and authentication under the
7 requirements of the United States Food and Drug Administration.

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

§16-67-7. Funding.

1 (a) The Secretary may use money appropriated to the Secretary and money received as a
2 gift, grant, or donation to pay for a grant under this chapter. The Secretary may solicit and accept
3 gifts, grants, and donations of any kind and from any source for purposes of this section.

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