EXPLAINER: Veterans Mental Health Innovations Act

Proposed Model Policy: "Veterans Mental Health Innovations Act"

Summary: Ibogaine is a psychoactive substance that a growing body of research shows can help treat opioid use disorder, traumatic brain injury, depression, and post-traumatic stress disorder by physically repairing damaged brain tissue. This model legislation is intended to authorize state ibogaine research and authorize participation in a larger multistate effort to complete a Food and Drug Administration (FDA) supervised clinical drug trial. The trial would seek approval of ibogaine as a treatment for opioid use disorder, depression, post-traumatic stress disorder, and other behavioral health conditions, especially those suffered by military veterans. If ibogaine is approved by the FDA to treat a medical condition, the legislation would allow licensed physicians to prescribe ibogaine administration for a patient under supervision.

Text:

AN ACT relating to the state's participation in a multistate consortium to conduct clinical trials overseen by the United States Food and Drug Administration using ibogaine as an investigational new drug for the treatment of opioid use disorder, co-occurring substance use disorder, and any other neurological or mental health conditions for which ibogaine demonstrates efficacy and to the administration of that treatment.

BE IT ENACTED BY THE LEGISLATURE OF THE <<STATE/COMMONWEALTH OF **NAME**>>:

SECTION 1. CHAPTER 001. IBOGAINE TREATMENT

CH. 001 – Subchapter A below provides language defining terms used in the legislation.

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 001.001. DEFINITIONS. In this chapter:
(1) "Comptroller" means the comptroller of public accounts. <<OR REPLACE WITH TREASURER or CONTROLLER, DEPENDING ON STATE>>
(2) "Consortium" means a group created by law in another state of the United States for the purpose of conducting drug development clinical trials with ibogaine.
(3) "Department" means the <<INSERT NAME OF STATE HEALTH DEPARTMENT>>
(4) "Ibogaine" means ibogaine and ibogaine-based therapeutics, including ibogaine analogs.

SUBCHAPTER B. PARTICIPATION IN MULTISTATE IBOGAINE CLINICAL RESEARCH TRIALS CONSORTIUM

CH. 001 – Subchapter B Sec. 001.101 FUNDING below provides language on the requirements for state participation in the multistate consortium to conduct clinical trials on ibogaine. The bill appropriates state funds to a state health agency, to be used to award a grant to a qualified research entity to conduct an ibogaine clinical trial. To qualify for the grant funding, the entity must meet several requirements, including the ability to secure matching funds. The grantee will also be required to have signed an agreement with the multistate consortium.

Sec. 001.101. FUNDING

(a) The sum of $XX,000,000 is appropriated from the state general fund in fiscal year 20XX-20XY to the <<INSERT NAME OF STATE HEALTH DEPARTMENT>> to award a grant to conduct a certified clinical drug development trial overseen by the United States Food and Drug Administration on the use of ibogaine for the treatment of opioid use disorder, co-occurring substance use disorder, or any other neurological or mental health condition for which ibogaine demonstrates efficacy. The department may award grants only to an entity that satisfies all of the following:

1. Is located within the <<STATE/COMMONWEALTH OF **NAME**>>.
2. Has a history of proven research and treatment of neurological diseases and expertise in substance dependence, emotional, and physical/neurological trauma.
3. Has a neurosurgery program with the requisite clinical and research facilities and that is:
    (i) staffed by professionals having expertise in the most challenging neurological and neurosurgical conditions; and
    (ii) capable of providing the necessary infrastructure and expertise to deliver cardiac intensive care services.
4. Has the ability to facilitate pioneering research and innovation in diagnosis and treatment of neurological conditions.
5. Has demonstrated to the department that the entity has a commitment for matching monies of gifts, grants and donations from sources other than this state in the amount of at least $XX,000,000 to conduct the certified clinical research study on the use of ibogaine for the treatment of neurological diseases.
6. Has signed an agreement with a consortium established by the government of another state within the United States of America, whether acting directly or through an agent or joint venture, that satisfies all of the following:
    (i) has submitted an investigational new drug (IND) application to the United States Food and Drug Administration in accordance with 21 C.F.R. Part 312; and
    (ii) has requested a breakthrough therapy designation for ibogaine from the United States Food and Drug Administration under 21 U.S.C. Section 356.

(b). The appropriation made in subchapter (a) of this section is exempt from the provisions of <<CITE STATUTORY SECTION DEFINING THE LAPSING OF APPROPRIATED FUNDS>>, relating to lapsing of appropriations.

(c) The department may not disburse the funding authorized in subchapter (a) until the applicant receives and the department verifies the receipt of matching funds from sources other than the state.

CH. 001 – Subchapter B Sec. 001.102 REPORTING REQUIREMENTS below details reporting requirements for grantees and the department. The grantee applicant selected to conduct clinical trials must submit a report on trial status and financial status to the overseeing department/agency quarterly. The department must submit a report, containing said information from the grantee to the state legislature by December 01 annually.

Sec. 001.102. REPORTING REQUIREMENTS.
(a) An applicant selected to conduct ibogaine drug development clinical trials shall quarterly prepare and submit to the department:
(1) a report on the progress of the drug development clinical trials conducted under this subchapter; and
(2) a financial status report, including information to verify expenditures of state funds and required matching funds.
(b) The department shall submit a report to the legislature on the progress of the drug development clinical trials and their related financial status conducted under this subchapter not later than December 1 of each year.

CH. 001 – Subchapter B Sec. 001.103 below establishes IP and other commercial rights, defines what constitutes the designation of such rights, creates a state fund for revenue, and outlines allowable management and investment practices for the revenue fund. This language ensures a wide range of work during the clinical trial is considered protected intellectual property rights or commercial rights (such as data, patents, treatment techniques),

Sec. 001.103. INTELLECTUAL PROPERTY AND OTHER RIGHTS; PERMANENT FUND AND ALLOCATION OF REVENUE ATTRIBUTABLE TO INTELLECTUAL PROPERTY

(a) There is hereby created an Ibogaine Intellectual Property Fund within the accounts of the <<STATE/COMMONWEALTH of **NAME**>> into which all revenue attributable to all intellectual property rights and other commercial rights that may arise from drug development clinical trials conducted by a multistate consortium under this subchapter during the period for which the trials are funded and any following period of commercialization shall be deposited.
(b) Such Fund shall be a permanent fund and the revenues accruing thereto shall not be spent, except that the earnings on its principal shall be distributed quarterly to programs that assist veterans or other at-risk populations in this state. <NOTE: *each state can customize the use of funds in this section, but in principle they should be targeted toward at-risk populations that could benefit from ibogaine research in a tangible way.*>

(c) The <<COMPTROLLER/CONTROLLER/TREASURER>> shall manage the fund and may invest its principal in high-grade securities. Examples of eligible investments include obligations issued or guaranteed by the United States, bonds or other evidences of indebtedness of this State or its political subdivisions, commercial paper from entities with investment-grade ratings, banker's acceptances, negotiable certificates of deposit, and certain bonds or debentures denominated in United States dollars with investment-grade ratings.
(d) For purposes of this section, intellectual property rights and other commercial rights arising from the drug development clinical trials conducted under this subchapter include any of the following as related to the trials:

(1) intellectual property, technology, and inventions;
(2) patents, trademarks, and licenses;
(3) proprietary and confidential information;
(4) trade secrets, data, and databases;
(5) tools, methods, and processes;
(6) treatment models or techniques;
(7) administration protocols; and
(8) works of authorship.

CH. 001 – Subchapter C below pertains to the administration of ibogaine treatment. If (and only if) ibogaine is approved by the USFDA to treat a medical condition, state-licensed physicians will be authorized to prescribe ibogaine for patients. Physicians will also be authorized to supervise ibogaine administration at an approved facility.

SUBCHAPTER C. IBOGAINE TREATMENT ADMINISTRATION

Sec. 001.201. APPLICABILITY. This subchapter applies only if ibogaine is approved by the United States Food and Drug Administration to treat a medical condition.

Sec. 001.202. MEDICAL SUPERVISION.
(a) A physician licensed under <<INSERT STATUTORY SECTION REFERENCE>> shall prescribe ibogaine for a patient; and
(b) A physician licensed under <<INSERT STATUTORY SECTION REFERENCE>> 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. 001.203. ADMINISTRATION UNDER FEDERAL LAW. This subchapter does not preclude a physician from administering ibogaine in accordance with federal law.

SECTION 2 below establishes a timeline for implementation of the legislation. The department must begin accepting proposals from grant applicants within 60 days of the effective date of the legislation. However, if a state agency determines a federal waiver or authorization is required to proceed with implementing a provision, that agency must request the waiver or authorization, and may delay implementation until it is granted.

SECTION 2. (a) 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.
(b) The department shall begin accepting proposals under <<INSERT REFERENCE TO SECTION 1 ABOVE>>, not later than the 60th day after the effective date of this Act.

SECTION 3 below is an optional provision which may be included to avoid waiting periods and delays in implementation. This language states that in accordance with a state's immediate effect policy, the provisions of the act take immediate effect upon passage of the legislation by a defined vote threshold (such as two-thirds of legislators).

(***OPTIONAL IMMEDIATE EFFECT PROVISION***) **SECTION 3**. This Act takes effect immediately if it receives a vote of <<INSERT VOTE THRESHOLD>> of all the members elected to each house, as provided by <<INSERT CONSTITUTIONAL REFERENCE TO IMMEDIATE EFFECT PROVISIONS>>

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