

HCS HBs 1717 & 1643 -- ALTERNATIVE THERAPIES (West)

COMMITTEE OF ORIGIN: Standing Committee on Emerging Issues

As specified in this bill, any person who acquires, uses, produces, possesses, transfers, or administers psilocybin for the person's own therapeutic use will not be in violation of State or local law and will not be subject to a civil fine, penalty, or sanction so long as the person meets the following conditions:

- (1) Is a veteran or a first responder, as those terms are defined in the bill;
- (2) Is 21 years of age or older;
- (3) Suffers from posttraumatic stress disorder, major depressive disorder, or a substance use disorder or requires end-of-life care;
- (4) Has enrolled in a study to study the use of psilocybin to treat posttraumatic stress disorder, major depressive disorder, or substance use disorders or for end-of-life care;
- (5) Informs the Department of Mental Health that the person plans to acquire, use, produce, possess, transfer, or administer psilocybin in accordance with this Section;
- (6) Provides the Department with documents specified in the bill. The Department must maintain the confidentiality of any personally identifiable protected information collected from anyone who provides information to the Department;
- (7) Use of psilocybin occurs only in the presence of a facilitator who meets requirements outlined in the bill;
- (8) Ensures that a laboratory licensed by the State to test controlled substances tests the psilocybin the person intends to ingest; and
- (9) The person limits the use of psilocybin to no more than 150 milligrams of psilocybin analyte (4-phosphoryloxy-N, N-dimethyltryptamine) during any 12-month period.

The Department must prepare and submit to the Governor, Lieutenant Governor, and the General Assembly annual reports on any information collected by the Department on the implementation and outcomes of the use of psilocybin.

This bill specifies that, a physician will not be subject to criminal or civil liability or sanction under the laws of this State for providing documentation that a person suffers from posttraumatic stress disorder, major depressive disorder, or a substance use disorder or requires end-of-life care, and no State agency or regulatory board can revoke, fail to renew, or take any other action against a physician's license issued under Chapter 334, RSMo, based solely on the physician's provision of documentation that a person suffers from posttraumatic stress disorder, major depressive disorder, or a substance use disorder or requires end-of-life care.

This bill establishes the "Veterans Mental Health Innovation Act."

The bill requires the Department of Health and Senior Services to award grants to conduct certified clinical drug development trials 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 must award grants only to an entity that satisfies criteria specified in the bill. The Department must begin accepting grant applications before November 1, 2026.

This bill creates the "Ibogaine Study Fund", which will consist of moneys appropriated to it by the General Assembly and any gifts, contributions, grants, or bequests received from Federal, private, or other sources. The State Treasurer will be custodian of the Fund. The State Treasurer can approve disbursements. The Fund will be used solely to award grants to conduct the certified clinical drug development trials.

An applicant selected to conduct ibogaine drug development clinical trials must quarterly prepare and submit to the Department:

- (1) A report on the progress of the drug development clinical trials conducted ; and
- (2) A financial status report, including information to verify expenditures of State funds and required matching funds.

The Department must submit a report to the General Assembly on the progress of the drug development clinical trials conducted

and the financial status of the trials before December 1st of each year.

This bill creates the "Ibogaine Intellectual Property Fund", which will consist of all revenue attributable to all intellectual property rights and other commercial rights that may arise from drug development clinical trials during the period for which the trials are funded and any following period of commercialization. The State Treasurer will be custodian of the Fund. The State Treasurer can approve disbursements. The Fund will be used solely for programs that assist veterans or other at-risk populations in this state.

Intellectual property rights and other commercial rights arising from the drug development clinical trials conducted 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.

If ibogaine is approved by the United States Food and Drug Administration to treat a medical condition, no person will prescribe ibogaine for a patient except a licensed physician. The physician must supervise the administration of ibogaine at a hospital or other licensed health care facility to ensure patient safety.

This bill also requires the Department, in collaboration with a hospital operated by the an institution of higher education in this State or contract research organizations conducting trials approved by the United States Food and Drug Administration in Missouri, to conduct a study on the efficacy of using alternative medicines and therapies, including, but not limited to, the use of psilocybin for the treatment of patients suffering from

posttraumatic stress disorder, major depressive disorder, substance use disorders, or who require end-of-life care.

The bill specifies that the study must include the therapeutic efficacy of using psilocybin in the treatment of veterans who suffer from posttraumatic stress disorder, major depressive disorder, or substance use disorders or who require end-of-life care, as well as a literature review and the submission of various reports.

The Department, any health care providers, and any person participating in the study will not be subjected to criminal or civil liability or sanction for the participation in the study, except in cases of gross negligence or willful misconduct. A physician will not be subject to criminal or civil liability or sanction under the laws of this State for referring a patient to the study under this section, and no state agency or regulatory board can revoke, fail to renew, or take any other action against a physician's license based solely on the physician's referral of a patient to the study under this section.

The Department must prepare and submit to the Governor, Lieutenant Governor and the General Assembly:

- (1) Quarterly reports on the progress of the study; and
- (2) A written report, submitted one year following the commencement of the study, which must:
 - (a) Contain the results of the study and any recommendations for legislative or regulatory action; and
 - (b) Highlight those clinical practices that appear to be most successful as well as any safety or health concerns. The Department must maintain the confidentiality of any personally identifiable protected information collected during the study.