SECOND REGULAR SESSION

SENATE BILL NO. 1581

103RD GENERAL ASSEMBLY

INTRODUCED BY SENATOR BEAN.

6783S.01I KRISTINA MARTIN, Secretary

AN ACT

To amend chapter 191, RSMo, by adding thereto seven new sections relating to ibogaine treatment.

Be it enacted by the General Assembly of the State of Missouri, as follows:

Section A. Chapter 191, RSMo, is amended by adding thereto seven new sections, to be known as sections 191.1610, 191.1613, 191.1616, 191.1619, 191.1622, 191.1625, and 191.1628, to read as follows:

191.1610. Sections 191.1610 to 191.1628 shall be known and may be cited as the "Veterans Mental Health Innovation Act".

191.1613. As used in sections 191.1610 to 191.1628, the following terms mean:

(1) "Applicant", an entity that applies for a grant under section 191.1616;

(2) "Consortium", 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", the department of health and senior services;

(4) "Ibogaine", ibogaine and ibogaine-based therapeutics, including, but not limited to, ibogaine analogs.

191.1616. 1. Subject to appropriation, the department shall award grants to conduct certified clinical drug

development trials overseen by the U.S. 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 shall award grants only to an entity that satisfies all of the following:

(1) Is located within this state;

(2) Has a history of proven research and treatment of neurological diseases and expertise in substance dependence, emotional trauma, and physical or neurological trauma;

(3) Has a neurosurgery program with the requisite clinical and research facilities and that is:

(a) Staffed by professionals having expertise in the most challenging neurological and neurosurgical conditions; and

(b) 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 moneys of gifts, grants, and donations from sources other than this state in an amount equal to the amount to be awarded to conduct the certified clinical research study on the use of ibogaine for the treatment of neurological diseases; and

(6) Has signed an agreement with a consortium established by the government of another state within the United States, whether acting directly or through an agent or joint venture, that satisfies all of the following:

(a) Has submitted an investigational new drug (IND) application to the U.S. Food and Drug Administration in accordance with 21 CFR 312; and

(b) Has requested a breakthrough therapy designation for ibogaine from the U.S. Food and Drug Administration under 21 U.S.C. Section 356.

2. The department shall not disburse the funding authorized in this section to an applicant until the applicant receives, and the department verifies the receipt of, matching funds from sources other than the state.

3. (1) There is hereby created in the state treasury the "Ibogaine Study Fund", which shall 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 shall be custodian of the fund. In accordance with sections 30.170 and 30.180, the state treasurer may approve disbursements. The fund shall be a dedicated fund and, upon appropriation, moneys in this fund shall be used solely to award grants under this section.

(2) Notwithstanding the provisions of section 33.080 to the contrary, any moneys remaining in the fund at the end of the biennium shall not revert to the credit of the general revenue fund.

(3) The state treasurer shall invest moneys in the fund in the same manner as other funds are invested. Any interest and moneys earned on such investments shall be credited to the fund.

191.1619. 1. 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 sections 191.1616 to 191.1622; and

(2) A financial status report, including information to verify expenditures of state funds and required matching funds.

2. The department shall submit a report to the general assembly on the progress of the drug development clinical trials conducted under sections 191.1616 to 191.1622 and the financial status of the trials before December first of each year.

191.1622. 1. There is hereby created in the state treasury the "Ibogaine Intellectual Property Fund", which shall consist of 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 sections 191.1616 to 191.1622 during the period for which the trials are funded and any following period of commercialization. The state treasurer shall be custodian of the fund. In accordance with sections 30.170 and 30.180, the state treasurer may approve disbursements. The fund shall be a dedicated fund and, upon appropriation, moneys in this fund shall be used solely for programs that assist veterans or other at-risk populations in this state.

2. Notwithstanding the provisions of section 33.080 to the contrary, any moneys remaining in the fund at the end of the biennium shall not revert to the credit of the general revenue fund.

3. The state treasurer shall invest moneys in the fund in the same manner as other funds are invested. Any

interest and moneys earned on such investments shall be credited to the fund.

4. For purposes of this section, intellectual property rights and other commercial rights arising from the drug development clinical trials conducted under sections 191.1616 to 191.1622 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.

191.1625. 1. The provisions of this section shall apply only if ibogaine is approved by the U.S. Food and Drug Administration to treat a medical condition.

2. No person shall prescribe ibogaine for a patient except a physician licensed under chapter 334.

3. A physician licensed under chapter 334 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.

4. The provisions of this section shall not preclude a physician from administering ibogaine in accordance with federal law.

191.1628. 1. If, before implementing any provision of sections 191.1610 to 191.1628, 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.

2. The department shall begin accepting grant applications under section 191.1616 before November 1, 2026.

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