STATE OF NEW YORK

7928

2021-2022 Regular Sessions

IN ASSEMBLY

June 1, 2021

Introduced by M. of A. L. ROSENTHAL -- read once and referred to the Committee on Health

AN ACT to amend the public health law, in relation to establishing the psychedelic research institute and the psychedelic substances therapeutic research program

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

Section 1. The public health law is amended by adding a new article 27-G to read as follows:

ARTICLE 27-G

PSYCHEDELIC RESEARCH INSTITUTE

Section 2788. Legislative findings.
2789. Definitions.
2790. The institute for therapeutic psychedelics research.
2791. Powers and duties.
2792. Research council.
2793. Advisory council.
2794. Reports by the commissioner.

§ 2788. Legislative findings. The legislature finds that recent research provides a growing body of evidence that 1. the use of psychedelics such as ibogaine, LSD, psilocybin and certain other psychedelic drugs in certain settings may provide a treatment for people struggling with a substance use disorder, including methamphetamine, opioids, and other addictive substances; 2. 3, 4-methylenedioxymethamphetamine (MDMA) may be efficacious in treatment of post-traumatic stress disorder (PTSD) and alcoholism; 3. psilocybin is a breakthrough therapy for severe depression and nicotine addiction; and 4. other psychedelic substances also may be efficacious in treatment of other illnesses and maladies. It is for the purpose of facilitating clinical programs for such research and investigation into the safety and efficacy of psychedelic substances

EXPLANATION--Matter in *italics* (underscored) is new; matter in brackets [-] is old law to be omitted.

LBD11370-02-1

for treatment of human illnesses and maladies that the psychedelic substances therapeutic research act is hereby enacted.

§ 2789. Definitions. For purposes of this article, the following terms shall have the following meanings:

1. "Psychedelic substance" means any substance listed in paragraph (d) of schedule I of section thirty-three hundred six of this chapter.

2. "Principal investigator" means an individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.

3. "Hospital" shall have the same meaning as defined pursuant to section twenty-eight hundred one of this chapter.

4. "Clinic" shall mean a site where a licensed or otherwise recognized practitioner or group provides care to patients and/or individuals seeking therapeutic interventions using psychedelic substances as listed herein.

5. "Internal review board" or "IRB" means an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects. In accordance with food and drug administration regulations, an IRB shall have the authority to approve, require modifications in (to secure approval), or disapprove research. IRB group review shall serve an important role in the protection of the rights, safety and welfare of human research subjects.

§ 2790. The institute for therapeutic psychedelics research. 1. There is hereby established within the department the public institute for therapeutic psychedelics research (ITPR). The institute shall have the central responsibility for administering the provisions of this article and otherwise coordinating the state's policies with respect to the use of psychedelic substances in treatment of substance use disorders, depression, post-traumatic stress disorder, end-of-life anxiety and other conditions.

2. The commissioner shall appoint a director of the institute and may assign such personnel within the amounts appropriated as is necessary to carry out the provisions of this article.

3. The state of New York shall designate such spaces within existing state-owned or operated facilities or buildings, or in conjunction with local departments of health, to establish a headquarters and, as appropriate clinics to conduct clinical trials of psychedelic substances for appropriate clinical outcomes, including, but not limited to, substance use disorders, depression, end-of-life anxiety and post-traumatic stress disorder.

§ 2791. Powers and duties. 1. The institute shall have the following powers and duties:

(a) to coordinate, develop and promote clinical programs and trials with appropriate methodologies to study and investigate the safety and efficacy of psychedelics for various outcomes, and assist in the coordination of extramural clinical studies, including as needed, access to psychedelic agents and other programmatic needs;

(b) to develop and promote programs of professional education and training and improvements in instrumentation as necessary adjuncts to such scientific investigations;

(c) to form an institutional review board to provide oversight in proposed clinical trials of psychedelic compounds, particularly to assist principal investigators at sites lacking formal institutional review board oversight;

(d) to develop and maintain a clearinghouse within the department for information collected on the safety and efficacy of psychedelic substances as well as to provide a registry for all outcomes of clinical trials and studies, including a catalog of the existing medical literature and the results of existing epidemiological studies;

(e) to develop and promote an outreach campaign directed toward people struggling with substance use disorder, depression, post-traumatic stress disorder, anxiety, alcoholism and nicotine addiction to promote the availability of psychedelic compounds as a treatment through clinical programs established hereunder as well as any clinical research and investigative programs that studies and investigates the safety and efficacy of psychedelic substances; and

(f) to promote the availability of any other supportive services for people struggling with substance use disorder, depression, post-traumatic stress disorder, anxiety, alcoholism and nicotine addiction as well as long term outcomes after treatment for such conditions or other aforementioned indications.

2. Personal data in any investigations, reports and information relating to the provisions of this article shall be kept confidential and anonymous, shall be afforded all of the protections provided by the provisions of paragraph (j) of subdivision one of section two hundred six of this chapter, and are hereby made subject to part two of title forty-two of the Code of Federal Regulations. The institute may however, from time to time, publish reports of such scientific investigations in such a manner as to assure that the identities of the individuals concerned cannot be ascertained.

§ 2792. Research council. 1. There shall be established within IPTR a research council composed of fifteen members; four members to be appointed by the temporary president of the senate, one member to be appointed by the minority leader of the senate, four members to be appointed by the speaker of the assembly, one member to be appointed by the minority leader of the assembly and five members to be appointed by the commissioner. The members shall be representative of recognized centers engaged in the scientific investigation of substance abuse disorders and/or the use of psychedelics in treatment of pertinent outcomes.

2. The research council shall be responsible for making recommendations to the institute for the purpose of carrying out the provisions of paragraphs (a) and (b) of subdivision one of section twenty-seven hundred ninety-one of this article, as well as appointing members of the internal review board as provided for in paragraph (c) of subdivision one of section twenty-seven hundred ninety-one of this article.

3. The council shall meet at least six times a year. Special meetings may be called by the chairperson and shall be called by him or her at the request of the commissioner.

4. The members of the council shall receive no compensation for their services, but shall be allowed their actual and necessary expenses incurred in the performance of their duties hereunder.

§ 2793. Advisory council. 1. There shall be established within IPTR an advisory council composed of thirteen members who shall be appointed in the following manner: three shall be appointed by the temporary president of the senate and one by the minority leader of the senate; three shall be appointed by the speaker of the assembly and one by the minority leader of the assembly; and five shall be appointed by the governor. The governor shall designate the chairperson of the advisory council. The members of the council shall be representative of the public, educa-

tional and medical institutions, local health departments, and nonprofit organizations, including organizations and individuals qualified through degree and/or experience presently providing psychedelic substances as a treatment modality for people struggling with a substance use disorder, depression, post-traumatic stress disorder, anxiety, alcoholism and nicotine addiction.

2. The advisory council shall be responsible for advising the commissioner with respect to the implementation of this article and shall make recommendations to the institute for the purpose of carrying out the provisions of paragraphs (d), (e), and (f) of subdivision one of section twenty-seven hundred ninety-one of this article.

3. The advisory council shall include at least four members of affected communities, provisions for a stipend, travel or other expenses to be established to provide insight and support from the community perspective in the development of clinical trial protocols.

4. The council shall meet at least four times a year. Special meetings may be called by the chairperson and shall be called by him or her at the request of the commissioner.

§ 2794. Reports by the commissioner. The institute shall make an initial preliminary report to the governor and the legislature of its findings, conclusions, and recommendations not later than December first, two thousand twenty-one, a second preliminary report of its findings, conclusions, and recommendations not later than December first, two thousand twenty-two, and a report of its findings, conclusions, and recommendations with regard to the progress made in developing, promoting and completing clinical evaluations not later than December first, two thousand twenty-three, and shall submit with its reports such legislative proposals as it deems necessary to implement its recommendations.

§ 2. The public health law is amended by adding a new article 33-AA to read as follows:

ARTICLE 33-AA

PSYCHEDELIC SUBSTANCES THERAPEUTIC RESEARCH ACT

Section 3397-j. Psychedelic substances therapeutic research program established; participation.
3397-k. State patient qualification board; composition; powers and duties.
3397-l. Psychedelic substances research program; cultivation and distribution.

§ 3397-j. Psychedelic substances therapeutic research program established; participation. 1. The psychedelic substances therapeutic research program is hereby established in the department. The commissioner shall promulgate rules and regulations necessary for the proper administration of the psychedelic substances therapeutic research program. In such promulgation, the commissioner shall take into consideration the reports of the psychedelics research institute and pertinent rules and regulations of the food and drug administration.

2. Participation in the psychedelics substances therapeutic research program shall be limited to persons eligible for participation by the internal review board (IRB)-approved inclusion and exclusion criteria of proposed clinical study. Outcome-directed clinical trials and evaluations may include persons addicted to opiates or methamphetamine, persons suffering from post-traumatic stress disorder (PTSD), or persons suffering from severe depression, as appropriate to the trial design registered with the public institute for therapeutic psychedelics research (ITPR) and the protocols specified in 42 CFR 11.

3. Where pertinent, participants in ITPR studies or evaluations should receive the current standard of care. Stakeholder community members will be consulted regarding proposed clinical trials for their or other studies, case series or other appropriate methodologies for evaluating the efficacy of psychedelic substances.

4. The commissioner, on behalf of the department, shall apply to the food and drug administration (FDA) for an investigational new drug permit for any of the psychedelic agents listed in section twenty-seven hundred eighty-eight of this chapter, including but not limited to ibogaine, psilocybin, LSD, cannabis, MDMA, DMT and other such agents within ninety days after the effective date of this section. The commissioner, on behalf of the department, may apply to the FDA for an investigational new drug (IND) permit for any other psychedelic substance as the commissioner deems appropriate. The commissioner shall continue to fulfill all of his or her duties hereunder unless and until this article is repealed.

§ 3397-k. State patient qualification board; composition; powers and duties. 1. The commissioner shall appoint a state patient qualification review board of no less than three nor more than five members. The state patient qualification review board shall be comprised of:

(a) a physician licensed to practice medicine in New York state and certified by the American board of internal medicine;

(b) a physician licensed to practice medicine in New York state and certified in psychiatry by the American board of psychiatry and neurology; and

(c) any other members that the commissioner may deem necessary, including individuals who may act in their capacity as a principal investigator as defined pursuant to section twenty-seven hundred eighty-nine of this chapter.

2. Members of such board shall be appointed for three-year terms, except that the terms of those first appointed shall be arranged so that as nearly as possible an equal number shall terminate annually. A vacancy occurring during a term shall be filled through an appointment by the commissioner for the unexpired term. The commissioner shall designate the chairperson of the board. Any member may be removed from the board at the discretion of the commissioner.

3. Each member of the board shall receive up to two hundred fifty dollars as prescribed by the commissioner for each day devoted to board work, not to exceed seventy-five hundred dollars in any one year and shall be reimbursed for necessary expenses.

4. Any hospital may establish a hospital patient qualification review committee subject to the rules and regulations promulgated by the commissioner. A hospital may designate a hospital human research review committee as set forth in section twenty-four hundred forty-four of this chapter to serve as a hospital patient qualification review committee.

5. The hospital patient qualification review committee shall review each recommendation and shall submit approved patient applications to the state patient qualification review board.

6. The state patient qualification review board shall review all principal investigator applicants for the psychedelic substances therapeutic research program and certify or refuse to certify their participation in such program.

7. The state patient qualification review board may delegate to a hospital patient qualification review committee the authority to approve or disapprove a patient's participation in such program.

8. The hospital human research review committee shall review each human research project proposed hereunder and shall certify to the hospital patient qualification review committee that such project meets the requirements of this article and article twenty-four-A of this chapter.

§ 3397-l. Psychedelic substances research program; cultivation and distribution. 1. The commissioner shall obtain psychedelic substances through whatever means the commissioner deems most appropriate, consistent with regulations promulgated by the food and drug administration and pursuant to the provisions of this article.

2. If, within a reasonable time, the commissioner is unable to obtain psychedelic substances pursuant to subdivision one of this section, the commissioner shall conduct an inventory of available sources of such substances in compliance with certified good manufacturing practices research grade standards pursuant to 21 CFR 211 and 21 CFR 210.1(a). Such inventory shall be for the purpose of determining the feasibility of obtaining controlled substances for use in the program. Upon conducting said inventory, the commissioner shall contract with the available source and obtain drug enforcement administration (DEA) licenses for the receipt of controlled substances.

3. If, within a reasonable time, the commissioner is unable to obtain psychedelic substances pursuant to subdivision one of this section, and notwithstanding the identification of an available source of such drugs in compliance with certified good manufacturing practices and FDA research grade standards, the commissioner is unable to obtain such drugs due to a refusal or failure of the DEA to issue the necessary licenses for the receipt of controlled substances, the commissioner shall contract with the available source and obtain the drugs without a DEA license.

4. The commissioner shall cause such psychedelic substances to be transferred to the clinics affiliated with the institute established pursuant to article twenty-seven-G of this chapter or to such research institute or hospital itself for distribution to certified patients pursuant to this article.

§ 3. Section 3350 of the public health law, as added by chapter 878 of the laws of 1972, is amended to read as follows:

§ 3350. Dispensing prohibition. Controlled substances may not be prescribed for, or administered or dispensed to [~~addicts~~] **people struggling with substance use disorder** or habitual users of controlled substances, except as provided by this title or title III **of this article or article thirty-three-AA of this chapter**.

§ 4. This act shall take effect on the one hundred eightieth day after it shall have become a law.