2026 Regular Session

ACT No. 956

ENROLLED

SENATE BILL NO. 43

BY SENATORS MCMATH, BARTHELEMY, BASS, BOUDREAUX, CARTER, CLOUD, CONNICK, DUPLESSIS, EDMONDS, FESI, HARRIS, HENRY, HENSGENS, JACKSON-ANDREWS, JENKINS, KLEINPETER, LUNEAU, MIGUEZ, MILLER, MIZELL, MYERS, OWEN, PRICE, SEABAUGH, SELDERS, STINE, TALBOT, WHEAT AND WOMACK AND REPRESENTATIVES ADAMS, BAYHAM, BERAULT, BILLINGS, BOYD, BOYER, BRASS, BROUSSARD, BRYANT, CARPENTER, CARVER, CHASSION, CHENEVERT, COATES, COX, CREWS, DESHOTEL, DEWITT, DICKERSON, DOMANGUE, ECHOLS, EGAN, FISHER, FREEMAN, FREIBERG, GLORIOSO, HEBERT, CHANCE HENRY, HILFERTY, HORTON, JACKSON, MIKE JOHNSON, KERNER, KNOX, LAFLEUR, JACOB LANDRY, LYONS, MACK, MCMAKIN, MELERINE, MILLER, MOORE, MURRAY, RISER, SAWYER, SCHAMERHORN, SPELL, ST. BLANC, STAGNI, TAYLOR, VENTRELLA, WALTERS, WRIGHT AND WYBLE

AN ACT

To enact Part IX of Chapter 1 of Title 28 of the Louisiana Revised Statutes of 1950, to be comprised of R.S. 28:211 and 212, relative to psychedelic-assisted therapy; to establish the Psychedelic-Assisted Therapy Initiative within the Louisiana Department of Health; to provide for clinical studies; to provide for clinical trial-enabling studies; to provide for drug development clinical trials; to provide for patient eligibility; to provide for funding; to provide for reporting; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1. Part IX of Chapter 1 of Title 28 of the Louisiana Revised Statutes of 1950, comprised of R.S. 28:211 and 212, is hereby enacted to read as follows:

PART IX. ALTERNATIVE THERAPIES

§211. Psychedelic-assisted therapy; clinical studies

A. For purposes of this Part, the following definitions shall apply:

(1) "Academic health center" means an organization that has a medical school, one or more other health professional schools or programs, and one or more affiliated teaching hospitals.

(2) "Drug developer" means a pharmaceutical company, biotechnology company, or contract development and manufacturing organization engaged in drug development and manufacturing.

(3) "Ibogaine" means ibogaine and ibogaine-based therapeutics, including ibogaine analogs.

(4) "Psychedelic medication" means ibogaine, ibogaine-based therapeutics, ibogaine analogs, MDMA, psilocybin, psilocybin-based therapeutics, and mechanistically-similar analogs.

(5) "Psychedelic-assisted therapy" means an intervention that includes the administration of a psychedelic medication to an individual in a controlled clinical setting and manualized, trauma-informed preparatory and integrative psychotherapy delivered by a qualified therapist to the individual before and after administration of the psychedelic medication.

B. There is hereby established within the Louisiana Department of Health, office of behavioral health, the Psychedelic-Assisted Therapy Initiative. The purpose of the initiative shall be all of the following:

(1) To identify academic health centers that are conducting clinical studies and clinical trial-enabling studies for the use of psychedelic-assisted therapy for the treatment of opioid use disorders, co-occurring substance use disorders, and treatment-resistant neurological or mental health conditions.

(2) To utilize the human service districts and authorities to identify eligible patients to participate in the program.

(3) To provide information to parishes on utilizing opioid settlement funds to enroll eligible patients residing in the parish to participate in the studies or to support clinical trial-enabling studies that allow for the initiation of clinical trials that may enroll patients who reside in the parish.

(4) To designate a state point of contact to coordinate with federal agencies and other states with regard to psychedelic-assisted therapy and related drug development.

C. The Louisiana Department of Health shall maintain a record of all academic health centers participating in the program.

D. Each participating academic health center shall maintain documentation ensuring compliance with state and federal regulations,

including all of the following:

(1) Ensuring that the clinical study will be conducted in accordance with a United States Food and Drug Administration investigational new drug application, expanded access program, or other federally authorized pathway.

(2) Ensuring that any study will be conducted on-site in a hospital, clinic, or research unit affiliated with the academic center, with confirmation of appropriate trial liability insurance coverage.

(3) Maintaining a United States Drug Enforcement Agency Schedule I research registration and any required state controlled substance registration.

(4) Obtaining Institutional Review Board approval for the clinical study.

(5) A clinical study protocol that includes all of the following:

(a) The study design, inclusion and exclusion criteria, objectives and endpoints, eligible patient visit schedule, and schedule of follow-up assessments.

(b) Informed consent procedures and participant safeguards.

(c) Data security and privacy protections, including for personal information.

(6) A drug administration plan for the clinical study that includes all of the following:

(a) The investigational drug product description, source, formulation, route of administration, and dosing regimen.

(b) A clinical staffing model and monitoring procedures for the administration of the investigational drug.

(c) Discharge criteria and transportation procedures for participants after psychedelic-assisted therapy.

(d) Procedures for the storage, handling, chain of custody, and disposal of controlled substances, and an accountability plan for violations of the procedures.

(7) A safety monitoring and risk management plan for the clinical study that includes all of the following:

(a) Medical and psychiatric screening procedures.

(b) On-site emergency response procedures.

(c) Adverse event and serious adverse event capture and reporting timelines.

(d) Predefined rules for pausing or stopping the clinical study.

(8) A fidelity plan for the clinical study that includes all of the following:

(a) Clinician licensure and qualification requirements.

(b) A training, supervision, and fidelity monitoring plan.

(c) Ethical safeguards and a participant complaint and grievance process.

E. Each academic health center may utilize the human service districts and authorities to identify eligible participants for the clinical studies. Eligible participants include individuals with opioid use disorders, co-occurring substance use disorders, and treatment-resistant neurological or mental health conditions.

F.(1) The academic health centers shall coordinate with parishes to utilize opioid settlement funds to enroll eligible patients residing in the parish to participate in the studies.

(2) In addition to utilization of opioid settlement funds, the department may seek and receive voluntary monies from any sources, including federal funds, gifts, grants, and donations, which shall be expended for the purposes provided for in this Section.

(3) To the extent feasible, the Louisiana Department of Health shall support and encourage the use of opioid settlement funds and other related monies as matching funds for federal or other external funding opportunities in support of Louisiana trial and trial-enabling studies.

G. No later than January first of each year, each academic health center participating in the program shall submit a progress report to the Louisiana Department of Health on clinical studies conducted by the academic health center. The Louisiana Department of Health shall determine the data required for inclusion in the report. The Louisiana Department of Health shall prepare

a compiled report of the data received from participating academic health centers and submit the report to the legislature by March first of each year.

H. To the extent feasible, participating academic health centers shall coordinate with other states that are conducting clinical trials for use of psychedelic-assisted therapy.

§212. Drug development of ibogaine and psychedelic medication treatments

A. An academic health center may enter into an agreement with a drug developer to establish a consortium for the purpose of conducting drug development clinical trials with ibogaine and psychedelic medication treatments and securing the United States Food and Drug Administration's approval of such treatments for the treatment of opioid use disorder, co-occurring substance use disorder, and any other neurological or mental health condition for which the treatments demonstrate efficacy.

B. A consortium seeking to conduct a drug development clinical trial may do all of the following:

(1) Submit an investigational new drug application to the United States Food and Drug Administration in accordance with 21 CFR Part 312.

(2) Seek a breakthrough therapy designation from the United States Food and Drug Administration in accordance with 21 U.S.C. 356.

(3) Enter into an agreement with a consortium established by the government of another state, whether acting through an agent or joint venture, that has taken both of the following actions:

(a) Has submitted an investigational new drug application to the United States Food and Drug Administration in accordance with 21 CFR Part 312.

(b) Has requested a breakthrough therapy designation for ibogaine from the United States Food and Drug Administration in accordance with 21 U.S.C. 356.

(4) Work with the United States Food and Drug Administration to coordinate the drug development trial in Louisiana with drug development trials that are being conducted in other states.

C.(1) Any revenue attributable to newly developed intellectual property and other commercial rights arising from trial-enabling and drug development clinical trial activity conducted by a consortium pursuant to this Section, during the period for which the trials are funded, and any following period of commercialization shall be allocated as follows:

(a) Not less than a two and one-half percent of net sales running royalty to the state.

(b) The remainder to the members of the consortium in the amounts specified by written agreement of the members.

(2) Intellectual property and other commercial rights arising from the drug development clinical trials conducted pursuant to this Section shall include any of the following as related to the trials:

(a) Intellectual property, technology, and inventions.

(b) Patents, trademarks, and licenses.

(c) Proprietary and confidential information.

(d) Trade secrets, data, and databases.

(e) Tools, methods, and processes.

(f) Treatment models or techniques.

(g) Administration protocols.

(h) Works of authorship.

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PRESIDENT OF THE SENATE

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SPEAKER OF THE HOUSE OF REPRESENTATIVES

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GOVERNOR OF THE STATE OF LOUISIANA

APPROVED: _____