SLS 26RS-83 **ORIGINAL**

2026 Regular Session

SENATE BILL NO. 43

BY SENATOR MCMATH

HEALTH SERVICES. Provides relative to psychedelic-assisted therapy. (8/1/26)

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, relative to psychedelic-assisted therapy; to establish the Psychedelic-Assisted Therapy Program within the Louisiana Department of Health; to provide for clinical studies; 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, is hereby enacted to read as follows:

PART IX. ALTERNATIVE THERAPIES

§211. Psychedelic-assisted therapy; clinical studies

A. For purposes of this Section, 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) "Psychedelic medication" means ibogaine, ibogaine-based therapeutics, ibogaine analogs, psilocybin, psilocybin-based therapeutics, and

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psilocybin analogs.

(3) "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 Program. The purpose of the program shall be:

(1) To assist academic health centers in conducting clinical studies for 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 allow parishes to utilize opioid settlement funds to enroll eligible patients residing in the parish to participate in the studies.

C. The Louisiana Department of Health shall approve academic health centers to participate in the program if a center has submitted documentation ensuring compliance with state and federal regulations, including:

(1) Ensuring that the clinical study will be conducted under an FDA investigational new drug application.

(2) Ensuring that the study will be conducted on-site of a hospital or clinic affiliated with the academic center.

(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:

(a) The study design, inclusion and exclusion criteria, objectives and

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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:

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

(b) When appropriate, an individualized dose-escalation regimen, including predefined dose levels, stopping rules, and therapeutic response evaluation criteria.

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

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

(e) 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:

(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:

(a) A psychotherapy manual that describes preparatory sessions, therapeutic support boundaries for the administration of the investigational drug during psychedelic-assisted therapy sessions, and integrative sessions.

(b) Therapist licensure and qualification requirements.

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

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

D. The department shall utilize the human service districts and authorities to identify eligible participants for the program. Eligible participants include individuals with opioid use disorders, co-occurring substance use disorders, and treatment-resistant neurological or mental health conditions.

E.(1) The department shall establish a process to allow 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.

F. No later than January first of each year, each academic health center participating in the program shall submit a progress report to the department on clinical studies conducted by the center. The department shall determine the data required for inclusion in the report. The department shall prepare a compiled report of the data received from participating academic health centers and submit the report to the legislature by February first of each year.

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

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The original instrument and the following digest, which constitutes no part of the legislative instrument, were prepared by Senate Legislative Services. The keyword, summary, and digest do not constitute part of the law or proof or indicia of legislative intent. [R.S. 1:13(B) and 24:177(E)]

DIGEST

SB 43 Original 2026 Regular Session McMath

Proposed law establishes the Psychedelic-Assisted Therapy Program within the La. Dept. of Health, office of behavioral health.

Proposed law establishes the following purposes of the program:

(1) To assist academic health centers in conducting clinical studies for use of psychedelic-assisted therapy involving ibogaine and psilocybin 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 allow parishes to utilize opioid settlement funds to enroll eligible patients residing in the parish to participate in the studies.

Proposed law requires the La. Dept. of Health to approve academic health centers to participate in the program if a center has submitted documentation ensuring compliance with state and federal regulations as provided in proposed law.

Proposed law requires the department to utilize the human service districts and authorities to identify eligible participants and to establish a process to allow parishes to utilize opioid settlement funds to enroll eligible patients residing in the parish to participate in the studies.

Proposed law authorizes the department to seek and receive federal funds, gifts, grants, and donations for the program in addition to utilizing opioid settlement funds.

Proposed law requires participating academic health centers to submit an annual progress report to the department and requires the department to submit a compiled report to the legislature by Feb. 1st of each year.

Proposed law requires the department and participating academic health centers to coordinate with other states that are conducting clinical trials for use of psychedelic-assisted therapy to the extent feasible.

Effective August 1, 2026.

(Adds R.S. 28:211)

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