

2026 Regular Session

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

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

1 AN ACT

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

8 Be it enacted by the Legislature of Louisiana:

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

11 **PART IX. ALTERNATIVE THERAPIES**

12 **§211. Psychedelic-assisted therapy; clinical studies**

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

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

17 **(2) "Drug developer" means a pharmaceutical company, biotechnology**

1 company, or contract development and manufacturing organization engaged in
2 drug development and manufacturing.

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

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

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

13 B. There is hereby established within the Louisiana Department of
14 Health, office of behavioral health, the Psychedelic-Assisted Therapy Initiative.

15 The purpose of the initiative shall be:

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

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

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

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

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

1 **including:**

2 **(1) Ensuring that the clinical study will be conducted under an FDA**
3 **investigational new drug application, expanded access program, or other**
4 **federally authorized pathway.**

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

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

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

11 **(5) A clinical study protocol that includes:**

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

14 **(b) Informed consent procedures and participant safeguards.**

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

17 **(6) A drug administration plan for the clinical study that includes:**

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

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

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

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

27 **(7) A safety monitoring and risk management plan for the clinical study**
28 **that includes:**

29 **(a) Medical and psychiatric screening procedures.**

1 **(b) On-site emergency response procedures.**

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

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

5 **(8) A fidelity plan for the clinical study that includes:**

6 **(a) Clinician licensure and qualification requirements.**

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

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

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

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

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

22 **G. No later than January first of each year, each academic health center**
23 **participating in the program shall submit a progress report to the department**
24 **on clinical studies conducted by the center. The department shall determine the**
25 **data required for inclusion in the report. The department shall prepare a**
26 **compiled report of the data received from participating academic health centers**
27 **and submit the report to the legislature by March first of each year.**

28 **H. To the extent feasible, participating academic health centers shall**
29 **coordinate with other states that are conducting clinical trials for use of**

1 psychedelic-assisted therapy.

2 §212. Drug development of ibogaine treatment

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

10 B. A consortium seeking to conduct an ibogaine drug development
11 clinical trial shall:

12 (1) Submit an investigational new drug application to the FDA in
13 accordance with 21 CFR Part 312.

14 (2) Seek a breakthrough therapy designation for ibogaine from the FDA
15 under 21 U.S.C. 356.

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

19 (a) Has submitted an investigational new drug application to the FDA in
20 accordance with 21 CFR Part 312.

21 (b) Has requested a breakthrough therapy designation for ibogaine from
22 the FDA under 21 U.S.C. 356.

23 (4) Work with the FDA to coordinate the drug development trial in
24 Louisiana with ibogaine drug development trials that are being conducted in
25 other states.

26 C.(1) Any revenue attributable to all intellectual property rights and
27 other commercial rights arising from drug development clinical trials
28 conducted by a consortium pursuant to this Section, during the period for which
29 the trials are funded, and any following period of commercialization shall be

- 1 **allocated as follows:**
- 2 **(a) Not less than twenty percent to the state.**
- 3 **(b) The remainder to the members of the consortium in the amounts**
- 4 **specified by written agreement of the members.**
- 5 **(2) Intellectual property rights and other commercial rights arising from**
- 6 **the drug development clinical trials conducted pursuant to this Section shall**
- 7 **include any of the following as related to the trials:**
- 8 **(a) Intellectual property, technology, and inventions.**
- 9 **(b) Patents, trademarks, and licenses.**
- 10 **(c) Proprietary and confidential information.**
- 11 **(d) Trade secrets, data, and databases.**
- 12 **(e) Tools, methods, and processes.**
- 13 **(f) Treatment models or techniques.**
- 14 **(g) Administration protocols.**
- 15 **(h) Works of authorship.**

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 Reengrossed

2026 Regular Session

McMath

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

Proposed law establishes the following purposes of the initiative:

- (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 participants.
- (3) To provide information to allow parishes utilizing opioid settlement funds to enroll eligible patients residing in the parish to participate in the studies or to support clinical trial-enabling 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 March 1st of each year.

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

Proposed law authorizes academic health centers to enter into agreements with drug developers to establish a consortium for purposes of conducting drug development clinical trials with ibogaine and provides for the process to establish a consortium.

Proposed law provides for the distribution of any revenue attributable to intellectual property rights and other commercial rights arising from drug development clinical trial.

Effective August 1, 2026.

(Adds R.S. 28:211 and 212)

Summary of Amendments Adopted by Senate

Committee Amendments Proposed by Senate Committee on Health and Welfare to the original bill

1. Changes requirements relative to the La. Dept. of Health's role in overseeing the clinical trials.
2. Changes requirements relative to required documentation for academic health centers conducting trials.
3. Authorizes academic health centers to enter into agreements with drug developers to conduct ibogaine clinical trials and participate in a consortium with other states.

Senate Floor Amendments to engrossed bill

1. Changes the Psychedelic-Assisted Therapy Program to an initiative within the La. Dept. of Health.
2. Moves certain program requirements from the La. Dept. of Health to the human service districts and authorities and the academic health centers.
3. Changes certain clinical study requirements for participating academic health centers.
4. Changes the submission date of the La Dept. of Health's report to the legislature.