

2019 Regular Session

HOUSE BILL NO. 169

BY REPRESENTATIVE HOFFMANN

Prefiled pursuant to Article III, Section 2(A)(4)(b)(i) of the Constitution of Louisiana.

HEALTH CARE: Authorizes a data system for collection of information on health effects and outcomes associated with medical marijuana

1 AN ACT

2 To amend and reenact R.S. 44:4.1(B)(26) and to enact R.S. 40:1046(A)(6), Subpart D of

3 Part III of Subchapter A of Chapter 5-D of Title 40 of the Louisiana Revised Statutes

4 of 1950, to be comprised of R.S. 40:1168.1 through 1168.6, and R.S. 40:1046(A)(6)

5 of Section 2 of Act No. 96 of the 2016 Regular Session of the Legislature of

6 Louisiana, relative to information concerning health effects, events, and outcomes

7 associated with patient use of medical marijuana; to authorize the Louisiana State

8 Board of Medical Examiners to establish and maintain an electronic data system for

9 the collection of such information; to require that the board collaborate with certain

10 medical education institutions in the design of the data system; to provide

11 specifications for components of the data system; to provide for reporting of data

12 into the system; to restrict disclosure and uses of data from the system; to provide for

13 a public records exception; to provide legislative findings and definitions; to

14 authorize administrative rulemaking; and to provide for related matters.

15 Be it enacted by the Legislature of Louisiana:

16 Section 1. R.S. 40:1046(A)(6) and Subpart D of Part III of Subchapter A of Chapter

17 5-D of Title 40 of the Louisiana Revised Statutes of 1950, comprised of R.S. 40:1168.1

18 through 1168.6, are hereby enacted to read as follows:

19 §1046. Recommendation of marijuana for therapeutic use; rules and regulations;

20 Louisiana Board of Pharmacy and the adoption of rules and regulations

1 relating to the dispensing of recommended marijuana for therapeutic use; the
2 Department of Agriculture and Forestry and the licensure of a production
3 facility

4 A.

5 * * *

6 (6) Physicians shall report adverse events and health outcomes associated
7 with a patient's use of medical marijuana to the data system provided for in R.S.
8 40:1168.1 et seq.

9 * * *

10 SUBPART D. MEDICAL MARIJUANA:
11 HEALTH INFORMATION DATA SYSTEM

12 §1168.1. Findings and purpose

13 A. The legislature hereby finds and declares that, while specific definitions
14 of the term vary, "evidence-based medicine" refers to the practice of medicine based
15 upon evidence derived from research and in a manner in which the physician bases
16 clinical decisions upon such evidence.

17 B. The purpose of this Subpart is to promote the practice of evidence-based
18 medicine in Louisiana through the creation of a system which facilitates the
19 collection and analysis of information on health effects, events, and outcomes
20 associated with the use of medical marijuana by patients in this state.

21 §1168.2. Definitions

22 For purposes of this Subpart, the following terms have the meaning ascribed
23 to them in this Section:

24 (1) "Adverse event" means any incident relating to the use of a drug
25 prescribed or recommended to a patient that may result in serious harm or injury to
26 the patient or in the patient's death.

27 (2) "Board" means the Louisiana State Board of Medical Examiners.

28 (3) "Data system" means the system authorized and provided for in R.S.
29 40:1168.3.

CODING: Words in ~~struck through~~ type are deletions from existing law; words underscored are additions.

1 (4) "Medical marijuana" means the therapeutic substance produced under the
2 authority of and in accordance with R.S. 40:1046.

3 (5) "Physician" has the meaning ascribed in R.S. 37:1262.

4 §1168.3. Data system; components; reporting; design in collaboration with medical
5 schools; public records exception

6 A. The board may create and maintain an electronic system for the collection
7 and analysis of clinical information associated with the use of medical marijuana by
8 patients. The system shall include, at minimum, the following components:

9 (1)(a) A component for the collection of data concerning adverse events
10 experienced by patients which are associated with the use of medical marijuana.

11 (b) The board shall design and administer the data system such that any of
12 the following persons may report an adverse event:

13 (i) The patient.

14 (ii) A family member of the patient.

15 (iii) A physician who prescribes or recommends medical marijuana to a
16 patient.

17 (iv) Any physician who treats a patient other than a physician who prescribes
18 or recommends medical marijuana to the patient.

19 (2)(a) A component for the collection of data concerning health outcomes
20 other than adverse events experienced by patients that are associated with the use of
21 medical marijuana.

22 (b) The board shall design and administer the data system such that reporting
23 of health outcomes is limited to physicians exclusively.

24 B. The board shall collaborate with the following institutions in designing
25 and implementing the data system:

26 (1) The medical school of the Louisiana State University Health Sciences
27 Center at New Orleans.

28 (2) The medical school of the Louisiana State University Health Sciences
29 Center at Shreveport.

1 (3) The Tulane University School of Medicine.

2 C. Except in cases of disclosure of data authorized by R.S. 40:1168.4(B), all
3 data in the data system shall be confidential and shall not be available for subpoena,
4 nor shall such information be disclosed, discoverable, or compelled to be produced
5 in any civil, criminal, administrative, or other proceeding. The data maintained in
6 the data system shall not be subject to any public records request nor shall any such
7 data be considered as a public record pursuant to R.S. 44:1 et seq.

8 §1168.4. Protection of health information; limitations on data use

9 A. The board shall maintain the data system in a secure environment which
10 complies, at minimum, with all applicable federal laws and regulations providing for
11 the protection of health information.

12 B.(1) The board may authorize and facilitate access to data in the system to
13 an outside party only if that party seeks the data for use in a bona fide medical
14 research effort which has been authorized by the institutional review board of the
15 organization conducting the research.

16 (2) The board shall have exclusive authority to determine whether an activity
17 qualifies as a bona fide medical research effort in accordance with Paragraph (1) of
18 this Subsection.

19 (3) Any disclosure of data in the system shall be subject to the approval of
20 the board.

21 §1168.5. Funding sources authorized for data system

22 The board is hereby authorized to receive and expend all funds as may be
23 necessary to implement and maintain the data system. Such funds may include,
24 without limitation, funds appropriated by the legislature, including any appropriation
25 of federal funds; funding provided by contract or other agreement with a
26 governmental entity; and any public or private donations, gifts, or grants from
27 governmental sources, individuals, corporations, nonprofit organizations, or other
28 business entities.

- (c) A physician who prescribes or recommends medical marijuana to a patient.
 - (d) Any physician who treats a patient other than a physician who prescribes or recommends medical marijuana to the patient.
- (2) A component for the collection of data concerning health outcomes other than adverse events experienced by patients that are associated with the use of medical marijuana. Requires the board to design and administer the data system such that reporting of health outcomes is limited to physicians exclusively.

Proposed law requires the board to collaborate with the medical schools of the LSU Health Sciences Centers at New Orleans and Shreveport and the Tulane University School of Medicine in designing and implementing the data system.

Proposed law requires the board to maintain the data system in a secure environment which complies, at minimum, with all applicable federal laws and regulations providing for the protection of health information.

Proposed law provides that the board may authorize and facilitate access to data in the system to an outside party only if that party seeks the data for use in a bona fide medical research effort which has been authorized by the institutional review board of the organization conducting the research. Stipulates that the board shall have exclusive authority to determine whether an activity qualifies as a bona fide medical research effort in accordance with proposed law, and that any disclosure of data in the system shall be subject to the approval of the board.

Proposed law provides that except for any disclosure of data specifically authorized by proposed law, all data in the data system shall be confidential and shall not be available for subpoena, nor shall such information be disclosed, discoverable, or compelled to be produced in any civil, criminal, administrative, or other proceeding. Stipulates that the data maintained in the data system shall not be subject to any public records request nor shall any such data be considered as a public record pursuant to present law relative to public records, R.S. 44:1 et seq.

Proposed law authorizes the board to receive and expend all funds as may be necessary to implement and maintain the data system. Provides that such funds may include, without limitation, funds appropriated by the legislature, including any appropriation of federal funds; funding provided by contract or other agreement with a governmental entity; and any public or private donations, gifts, or grants from governmental sources, individuals, corporations, nonprofit organizations, or other business entities.

Proposed law requires the board to promulgate administrative rules as necessary to implement proposed law.

(Amends R.S. 44:4.1(B)(26); Adds R.S. 40:1046(A)(6) and 1168.1-1168.6 and R.S. 40:1046(A)(6) of §2 of Act No. 96 of the 2016 R.S.)