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

AN ACT

To amend and reenact R.S. 44:4.1(B)(26) and to enact R.S. 40:1046(A)(6), Subpart D of Part III of Subchapter A of Chapter 5-D of Title 40 of the Louisiana Revised Statutes of 1950, to be comprised of R.S. 40:1168.1 through 1168.6, and R.S. 40:1046(A)(6) of Section 2 of Act No. 96 of the 2016 Regular Session of the Legislature of Louisiana, relative to information concerning health effects, events, and outcomes associated with patient use of medical marijuana; to authorize the Louisiana State Board of Medical Examiners to establish and maintain an electronic data system for the collection of such information; to require that the board collaborate with certain medical education institutions in the design of the data system; to provide specifications for components of the data system; to provide for reporting of data into the system; to restrict disclosure and uses of data from the system; to provide for a public records exception; to provide legislative findings and definitions; to authorize administrative rulemaking; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1. R.S. 40:1046(A)(6) and Subpart D of Part III of Subchapter A of Chapter 5-D of Title 40 of the Louisiana Revised Statutes of 1950, comprised of R.S. 40:1168.1 through 1168.6, are hereby enacted to read as follows:

§1046. Recommendation of marijuana for therapeutic use; rules and regulations; Louisiana Board of Pharmacy and the adoption of rules and regulations

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

A.

* * *

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

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SUBPART D. MEDICAL MARIJUANA:

HEALTH INFORMATION DATA SYSTEM

§1168.1. Findings and purpose

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

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

§1168.2. Definitions

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

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

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

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

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

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

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

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

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

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

(i) The patient.

(ii) A family member of the patient.

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

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

(2)(a) 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.

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

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

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

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

(3) The Tulane University School of Medicine.

C. Except in cases of disclosure of data authorized by R.S. 40:1168.4(B), 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. 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 R.S. 44:1 et seq.

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

A. The board shall 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.

B.(1) 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.

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

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

§1168.5. Funding sources authorized for data system

The board is hereby authorized to receive and expend all funds as may be necessary to implement and maintain the data system. 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.

§1168.6. Rulemaking

The board shall promulgate all such rules in accordance with the Administrative Procedure Act as are necessary to implement the provisions of this Subpart.

Section 2. R.S. 44:4.1(B)(26) is hereby amended and reenacted to read as follows:

§4.1. Exceptions

* * *

B. The legislature further recognizes that there exist exceptions, exemptions, and limitations to the laws pertaining to public records throughout the revised statutes and codes of this state. Therefore, the following exceptions, exemptions, and limitations are hereby continued in effect by incorporation into this Chapter by citation:

* * *

(26) R.S. 40:3.1, 31.14, 31.27, 39.1, 41, 73, 95, 96, 526, 528, 1007, 1061.21, 1079.18, 1081.10, 1105.6, 1105.8, 1133.8, 1168.3, 1171.4, 1203.4, 1231.4, 1379.1.1(D), 1379.3, 2009.8, 2009.14, 2010.5, 2017.9, 2018, 2018.5, 2019, 2020, 2106, 2138, 2532, 2845.1

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Section 3. R.S. 40:1046(A)(6) of Section 2 of Act No. 96 of the 2016 Regular Session of the Legislature of Louisiana is hereby enacted to read as follows:

Section 2. R.S. 40:1046 is hereby amended and reenacted to read as follows:

§1046. Prescription of marijuana for therapeutic use; rules and regulations; Louisiana Board of Pharmacy and the adoption of rules and regulations relating to the dispensing of prescribed marijuana for therapeutic use; the Department of Agriculture and Forestry and the licensure of a production facility

A.

* * *

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

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DIGEST

The digest printed below was prepared by House Legislative Services. It constitutes no part of the legislative instrument. The keyword, one-liner, abstract, 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)]

HB 169 Engrossed 2019 Regular Session Hoffmann

Abstract: Authorizes the La. State Board of Medical Examiners to create and maintain a data system for collection of information on health effects and outcomes associated with medical marijuana.

Present law authorizes physicians who are domiciled in La. and licensed by and in good standing with the La. State Board of Medical Examiners, referred to hereafter as the "board", to recommend medical marijuana for therapeutic use by patients clinically diagnosed as suffering from a debilitating medical condition. Authorizes physicians to prescribe, rather than recommend, medical marijuana for treatment of a patient's debilitating medical condition if and when the U.S. Drug Enforcement Administration reclassifies marijuana from a Schedule I drug to a Schedule II drug. Defines "debilitating medical condition" to mean cancer, glaucoma, Parkinson's disease, positive status for human immunodeficiency virus, acquired immune deficiency syndrome, cachexia or wasting syndrome, seizure disorders, epilepsy, spasticity, severe muscle spasms, intractable pain, Crohn's disease, muscular dystrophy, multiple sclerosis, post traumatic stress disorder, and certain conditions associated with autism spectrum disorder.

Proposed law retains present law and requires that La.-licensed physicians report adverse events and health outcomes associated with a patient's use of medical marijuana to the data system provided for in proposed law. Defines "adverse event" as any incident relating to the use of a drug prescribed or recommended to a patient that may result in serious harm or injury to the patient or in the patient's death.

Proposed law provides that its purpose is to promote the practice of evidence-based medicine in La. through the creation of a system which facilitates the collection and analysis of information on health effects, events, and outcomes associated with the use of medical marijuana by patients in this state.

Proposed law authorizes the board to create and maintain an electronic system for the collection and analysis of clinical information associated with the use of medical marijuana by patients. Requires that the system include, at minimum, the following components:

(1) A component for the collection of data concerning adverse events experienced by patients which are associated with the use of medical marijuana. Requires the board to design and administer the data system such that any of the following persons may report an adverse event:

(a) The patient.

(b) A family member of the patient.

(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.)