2019 Regular Session

HOUSE BILL NO. 169

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BY REPRESENTATIVE HOFFMANN AND SENATOR THOMPSON

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 institutions in the design of the data system; to provide specifications for components 11 of the data system; to provide for reporting of data into the system; to restrict 12 disclosure and uses of data from the system; to provide for a public records 13 exception; to provide legislative findings and definitions; to authorize administrative 14 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 21 relating to the dispensing of recommended marijuana for therapeutic use; the 22 Department of Agriculture and Forestry and the licensure of a production 23 facility

	HB NO. 169 <u>ENROLLED</u>
1	A.
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3	(6) Physicians shall report adverse events and health outcomes associated
4	with a patient's use of medical marijuana to the data system provided for in R.S.
5	40:1168.1 et seq.
6	* * *
7	SUBPART D. MEDICAL MARIJUANA:
8	HEALTH INFORMATION DATA SYSTEM
9	§1168.1. Findings and purpose
10	A. The legislature hereby finds and declares that, while specific definitions
1	of the term vary, "evidence-based medicine" refers to the practice of medicine based
12	upon evidence derived from research and in a manner in which the physician bases
13	clinical decisions upon such evidence.
14	B. The purpose of this Subpart is to promote the practice of evidence-based
15	medicine in Louisiana through the creation of a system which facilitates the
16	collection and analysis of information on health effects, events, and outcomes
17	associated with the use of medical marijuana by patients in this state.
18	§1168.2. Definitions
19	For purposes of this Subpart, the following terms have the meaning ascribed
20	to them in this Section:
21	(1) "Adverse event" means any incident relating to the use of a drug
22	prescribed or recommended to a patient that may result in serious harm or injury to
23	the patient or in the patient's death.
24	(2) "Board" means the Louisiana State Board of Medical Examiners.
25	(3) "Data system" means the system authorized and provided for in R.S.
26	<u>40:1168.3.</u>

 $\underline{(4)\ "Medical\,marijuana"\,means\,the\,therapeutic\,substance\,produced\,under\,the}$

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

authority of and in accordance with R.S. 40:1046.

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1	§1168.3. Data system; components; reporting; design in collaboration with medical
2	schools; public records exception
3	A. The board may create and maintain an electronic system for the collection
4	and analysis of clinical information associated with the use of medical marijuana by
5	patients. The system shall include, at minimum, the following components:
6	(1)(a) A component for the collection of data concerning adverse events
7	experienced by patients which are associated with the use of medical marijuana.
8	(b) The board shall design and administer the data system such that any of
9	the following persons may report an adverse event:
10	(i) The patient.
11	(ii) A family member of the patient.
12	(iii) A physician who prescribes or recommends medical marijuana to a
13	patient.
14	(iv) Any physician who treats a patient other than a physician who prescribes
15	or recommends medical marijuana to the patient.
16	(2)(a) A component for the collection of data concerning health outcomes
17	other than adverse events experienced by patients that are associated with the use of
18	medical marijuana.
19	(b) The board shall design and administer the data system such that reporting
20	of health outcomes is limited to physicians exclusively.
21	B. The board shall collaborate with the following institutions in designing
22	and implementing the data system:
23	(1) The medical school of the Louisiana State University Health Sciences
24	Center at New Orleans.
25	(2) The medical school of the Louisiana State University Health Sciences
26	Center at Shreveport.
27	(3) The Tulane University School of Medicine.
28	(4) The Pennington Biomedical Research Center.
29	(5) The College of Nursing and Allied Health at Southern University and
30	Agricultural and Mechanical College.

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1	(6) The Xavier University of Louisiana College of Pharmacy.
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

governmental entity; and any public or private donations, gifts, or grants from

governmental sources, individuals, corporations, nonprofit organizations, or other

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business entities.

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81168 6	Rulemaking	

1	§1168.6. Rulemaking
2	The board shall promulgate all such rules in accordance with the
3	Administrative Procedure Act as are necessary to implement the provisions of this
4	Subpart.
5	Section 2. R.S. 44:4.1(B)(26) is hereby amended and reenacted to read as follows:
6	§4.1. Exceptions
7	* * *
8	B. The legislature further recognizes that there exist exceptions, exemptions,
9	and limitations to the laws pertaining to public records throughout the revised
10	statutes and codes of this state. Therefore, the following exceptions, exemptions, and
11	limitations are hereby continued in effect by incorporation into this Chapter by
12	citation:
13	* * *
14	(26) R.S. 40:3.1, 31.14, 31.27, 39.1, 41, 73, 95, 96, 526, 528, 1007, 1061.21,
15	1079.18, 1081.10, 1105.6, 1105.8, 1133.8, <u>1168.3</u> , 1171.4, 1203.4, 1231.4,
16	1379.1.1(D), 1379.3, 2009.8, 2009.14, 2010.5, 2017.9, 2018, 2018.5, 2019, 2020,
17	2106, 2138, 2532, 2845.1
18	* * *
19	Section 3. R.S. 40:1046(A)(6) of Section 2 of Act No. 96 of the 2016 Regular
20	Session of the Legislature of Louisiana is hereby enacted to read as follows:
21	Section 2. R.S. 40:1046 is hereby amended and reenacted to read as follows:
22	§1046. Prescription of marijuana for therapeutic use; rules and regulations;
23	Louisiana Board of Pharmacy and the adoption of rules and
24	regulations relating to the dispensing of prescribed marijuana for
25	therapeutic use; the Department of Agriculture and Forestry and the

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licensure of a production facility

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1	(6) Physicians shall report adverse events and health outcomes
2	associated with a patient's use of medical marijuana to the data system
3	provided for in R.S. 40:1168.1 et seq.
4	* * *
	SPEAKER OF THE HOUSE OF REPRESENTATIVES
	PRESIDENT OF THE SENATE
	GOVERNOR OF THE STATE OF LOUISIANA

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APPROVED: