SLS 14RS-597 ORIGINAL

Regular Session, 2014

SENATE BILL NO. 259

BY SENATOR JOHNS

HEALTH CARE. Provides relative to Louisiana health care consumers' right to know. (8/1/14)

1 AN ACT

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To amend and reenact R.S. 40:1300.111 through 1300.114 and to enact R.S. 40:1300.115 and 1300.116, relative to Louisiana health care consumers' right to know; to provide for legislative findings; to provide for powers and duties of the department; to provide for the Health Data Panel; to provide for the release of certain information; to provide for data use agreements; to provide for penalties for violations; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1. R.S. 40:1300.111 through 1300.114 are hereby amended and reenacted and R.S. 40:1300.115 and 1300.116 are hereby enacted to read as follows:

§1300.111. Findings

The legislature finds that as a result of rising health care costs, the shortage of health professionals and health care services in many areas of the state, and the concerns expressed by consumers, health care providers, third-party payers, and others involved with making informed decisions regarding health care services, treatment, and coverage, there is a need to have access to provider specific health care cost, quality, and outcome data on health care facilities, health care providers,

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and health plans as well as continued access to global patterns and trends in the availability, use, and charges for health care services and the associated health

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The legislature further finds that as a result of the rapidly expanding availability and access to patient sensitive health care data, the citizens of Louisiana deserve protection of their patient encounter data to the greatest

extent possible relative to health care data reporting and dissemination of

protected health information datasets for use in research projects intended to

improve the population health of Louisiana's citizens.

§1300.112. Data collection; powers and duties of the Department of Health and Hospitals

The Department of Health and Hospitals, in consultation with the Health Data Panel, shall:

- (1) Identify and define the health care cost, quality, and performance data elements to be reported to the Department of Health and Hospitals in accordance with existing national and international data standards for consumers' meaningful comparison of costs for specific health care services and specific quality of care measures between and among medical facilities, health care providers, and health plans.
- (2) Develop standards of accuracy, quality, timeliness, economy, and efficiency for the provision of data.
- (3) Identify the most practical methods to collect, transmit, and share required health care data as described in this Part.
- (4) Utilize, wherever practical, existing administrative data bases, and modalities of data collection to provide the required data.
- (5) Ensure confidentiality of patients by enforcing appropriate rules and regulations at least as stringent as those regulations applicable to covered entities promulgated under the Health Insurance Portability and Accountability Act privacy regulations, 42 CFR Part 164.

1	(6) Maintain the computerized database of consumer's personal health
2	information in a secure environment in compliance with federal laws ensuring
3	the security of the system containing such data. In the event of a data breach
4	or suspected data breach, the Department of Health and Hospitals shall within
5	thirty days notify any resident of the state whose personal information was, or
6	is reasonably believed to have been, acquired by an unauthorized person.
7	(7) Coordinate with the Louisiana Department of Insurance on all matters of
8	health plan cost, quality, and performance data to be collected from health plans
9	licensed to offer health insurance coverage in Louisiana. Such data shall exclude
10	premium data and information related to the development of premiums.
11	(7)(8) Include appropriate risk-adjustment measures into the production of
12	all health care cost, quality, and performance data issued to account for variation in
13	facility size, location, and patient acuity levels.
14	(8)(9) Provide the process for Internet publication of provider and health plan
15	specific cost, quality, and performance data collected pursuant to this Part for access
16	and use by a consumer or requesting entity.
17	(9)(10) Ensure that data released pursuant to this Part shall not include any
18	identifier which is listed in 45 CFR 164.514(b) as being necessary to be removed in
19	order for the data to be de-identified within the meaning of 45 CFR 164.514(a).
20	(10)(11) Promulgate rules and regulations, in accordance with the
21	Administrative Procedure Act, to carry out the provisions of this Part.
22	(11)(12) Implement the initial phase of the Internet website created pursuant
23	to this Part on or before April 30, 2009.
24	(12)(13) In the event that sufficient funds are not appropriated to implement
25	this Part, to include the collection, storage, analysis, and dissemination of data to
26	participating agencies, organizations, and the general public, the application and
27	enforcement of this Part shall be suspended pending the appropriation of sufficient
28	funds, and all accumulated health care data shall be stored with appropriate
29	confidentiality safeguards, destroyed, or transferred to another appropriate agency

1	or organization in accordance with state law.
2	§1300.113. Health Data Panel; advisory council to the secretary of the Department
3	of Health and Hospitals
4	A. The Department of Health and Hospitals shall create the Health Data
5	Panel. The purpose of the Health Data Panel shall be to make recommendations to
6	the secretary of the Department of Health and Hospitals for the implementation of
7	the requirements of this Part. The Health Data Panel shall consider the provisions set
8	forth in R.S. 40:1300.112.
9	B. Members of the Health Data Panel shall be appointed by the secretary and
10	shall represent all interests involved in the collection and publication of provider and
11	health plan specific cost, quality, and performance data elements. Members shall
12	include but not be limited to health care purchasers, hospitals and other service
13	providers, consumer and patient advocacy groups, quality improvement and health
14	information technology groups, physicians, and any other individuals or groups as
15	deemed necessary by the secretary.
16	C. The Health Data Panel shall consider the provisions set forth in R.S.
17	40:1300.112. Changes to the mandatory health care data elements or the
18	methodology by which data shall be reported by health care providers and
19	health plans to the Department of Health and Hospitals shall be approved by
20	a majority vote of the members of the Health Data Panel and promulgated by
21	a rule in accordance with the Administrative Procedure Act by the Department
22	of Health and Hospitals.
23	$\underline{\mathbf{D}}_{ullet}$ The secretary or his designee shall serve as the chairman of the meetings
24	of the Health Data Panel. The secretary shall convene meetings of the Health
25	Data Panel on an annual basis and as needed to fulfill the provisions of this
26	Part. The secretary may shall use the recommendations of the Health Data Panel to
27	fulfill the Department of Health and Hospitals' responsibilities as set forth in this
28	Part.

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D. E. Members of the Health Data Panel shall serve without compensation.

§1300.114. Release of information 1 2 A. Notwithstanding any other provision of the law to the contrary, data 3 collected pursuant to this Part may be disclosed for research purposes but only under the following circumstances: 4 5 (1) The requesting entity is recognized as a health care research organization, focused on the improvement of healthcare outcomes through 6 7 education and community engagement. 8 (2) The data sought to be used for research qualifies as de-identified 9 personal health information as defined in 45 CFR 164.514. 10 **B.(1)** All requests for data shall be submitted to Department of Health 11 and Hospitals, then reviewed and approved by a majority vote of the Health 12 Data Panel. 13 (2) The data request shall include: (a) A description of the requesting entity, including its ownership 14 15 structure. (b) Rationale for the study or data use. 16 17 (c) A summary of the project or study plan, including a project timeline, definition of project scope, and justification for the particular fields and records 18 19 necessary for the project or study. 20 (d) Signed data use agreement pursuant to R.S. 40:1300.115 by the 21 requesting entity and any subcontractors. 22 (e) Affirmation that the data requesting entity shall destroy all data in its entirety upon completion of the research project. 23 24 §1300.115. Data use agreement The Department of Health and Hospitals shall enter into a data use 25 26 agreement outlining the permitted uses and disclosures of the de-identified 27 personal health information. The agreement shall include at a minimum the following: 28 29 (1) A description of the requesting entity, including its ownership

1	structure.
2	(2) Rationale for the study or data use.
3	(3) A summary of the project or study plan, including a project timeline,
4	definition of project scope, and justification for the particular fields and records
5	necessary for the project or study.
6	(4) Identify all parties who may use or receive the information and
7	prohibit any recipient from using or further disclosing the data, except as
8	permitted by the agreement.
9	(5) Include an affirmation that data shall be used only for the stated
10	purpose, and that no attempts shall be made to combine data provided for in the
11	request with other data to identify confidential information.
12	(6) Require the recipient to use and demonstrate that appropriate
13	safeguards are in place to prevent the use or disclosure of data that is not
14	permitted by the agreement.
15	(7) Require the recipient to report to the Department of Health and
16	Hospitals any unauthorized use or disclosure of data.
17	(8) Require the recipient to ensure that any agents, including
18	subcontractors to whom it provides the information, agree to the data use
19	restrictions.
20	(9) Detail the method by which the data will be destroyed after the
21	qualifying research project is completed.
22	(10) Signed by the requesting health care research entity and any
23	subcontractors. Any future subcontractors shall be disclosed and approved by
24	the Department of Health and Hospitals.
25	(11) Prohibit the recipient from identifying the information or contacting
26	the individuals.
27	§1300. <del>114</del> <u><b>116</b></u> . Violations; penalties
28	A. All state agencies and health professional licensing, certification, or
29	registration boards and commissions, which collect, maintain, or distribute health

data, shall provide to the Department of Health and Hospitals such data as are necessary for the department to carry out its responsibilities as defined in this Part.

B. All health care providers licensed by the state, including but not limited to hospitals, outpatient surgical facilities, and outpatient clinical facilities shall submit information in the manner and form prescribed in rules and regulations promulgated by the Department of Health and Hospitals pursuant to this Part.

C. Any person, firm, corporation, organization, or institution that violates any of the provisions of this Part or any rules and regulations promulgated thereunder regarding patient confidentiality of information shall be guilty of a misdemeanor and upon conviction thereof shall be punished by a fine of not less than five hundred dollars nor more than one thousand dollars or by imprisonment not exceeding one month, or both. Each day of the violation shall constitute a separate offense.

D. Any person, firm, corporation, organization, or institution knowingly violating any of the provisions of this Part or any rules and regulations promulgated thereunder shall be guilty of a misdemeanor and upon a plea of guilty, a plea of nolo contendere or conviction, shall be punished by a fine of not more than one thousand dollars.

E. Renewal of state licenses issued by the Department of Health and Hospitals, Department of Insurance or health professional licensing, certification, or registration boards and commissions shall be predicated in part on compliance with data reporting requirements of this Part and rules and regulations promulgated thereunder. Prior to relicensing, the secretary of the Department of Health and Hospitals shall confirm compliance with data reporting requirements in writing to the appropriate permitting or licensing authority. The permit, certification, or license of any health care provider, health plan, or facility covered by this Part shall be suspended until such time as the required data is submitted to the Department of Health and Hospitals.

The original instrument and the following digest, which constitutes no part of the legislative instrument, were prepared by Christopher D. Adams.

## DIGEST

Johns (SB 259)

Present law provides for the health care consumers' right to know.

<u>Proposed law</u> adds to the legislative findings to find that as a result of the rapidly expanding availability and access to patient sensitive health care data, the citizens of Louisiana deserve protection of their patient encounter data to the greatest extent possible relative to health care data reporting and dissemination of protected health information datasets for use in research projects intended to improve the population health of Louisiana's citizens.

<u>Proposed law</u> amends <u>present law</u> to include to that the Department of Health and Hospitals (the department), in consultation with the Health Data Panel, shall maintain the computerized database of consumer's personal health information in a secure environment in compliance with federal laws ensuring the security of the system containing such data. Further, in the event of a data breach or suspected data breach, the department shall within 30 days notify any resident of the state whose personal information was, or is reasonably believed to have been, acquired by an unauthorized person.

<u>Present law</u> provides the department shall create the Health Data Panel, and the purpose of the Health Data Panel shall be to make recommendations to the secretary of the department for the implementation of the requirements of <u>present law</u>. <u>Present law</u> provides the Health Data Panel shall consider the provisions set forth in <u>present law</u>.

<u>Proposed law</u> amends <u>present law</u> and removes the provision that provides the Health Data Panel shall consider the provisions set forth in <u>present law</u>.

<u>Present law</u> provides members of the Health Data Panel shall be appointed by the secretary and shall represent all interests involved in the collection and publication of provider and health plan specific cost, quality, and performance data elements. Further, members shall include but not be limited to health care purchasers, hospitals and other service providers, consumer and patient advocacy groups, quality improvement and health information technology groups, physicians, and any other individuals or groups as deemed necessary by the secretary.

<u>Proposed law</u> provides the Health Data Panel shall consider the provisions set forth in <u>present law</u>. Further provides that changes to the mandatory health care data elements or the methodology by which data shall be reported by health care providers and health plans to the department shall be approved by a majority vote of the members of the Health Data Panel and promulgated by a rule in accordance with the Administrative Procedure Act by the department.

<u>Present law</u> provides the secretary or his designee shall serve as the chairman of the meetings of the Health Data Panel. Further, the secretary may use the recommendations of the Health Data Panel to fulfill the department's responsibilities as set forth in <u>present law</u>.

<u>Proposed law</u> provides the secretary or his designee shall serve as the chairman of the meetings of the Health Data Panel. The secretary shall convene meetings of the Health Data Panel on an annual basis and as needed to fulfill the provisions of <u>present law</u>. Further, the secretary shall use the recommendations of the Health Data Panel to fulfill the department's responsibilities as set forth in <u>present law</u>.

<u>Proposed law</u> provides data collected pursuant to <u>present law</u> may be disclosed for research purposes but only under the following circumstances:

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Coding: Words which are struck through are deletions from existing law; words in **boldface type and underscored** are additions.

- (1) The requesting entity is recognized as a health care research organization, focused on the improvement of healthcare outcomes through education and community engagement.
- (2) The data sought to be used for research qualifies a de-identified personal health information as defined in 45 CFR 164.514.

<u>Proposed law</u> provides all requests for data shall be submitted to the department, then reviewed and approved by a majority vote of the Health Data Panel.

<u>Proposed law</u> provides the data request shall include:

- (1) A description of the requesting entity, including its ownership structure.
- (2) Rationale for the study or data use.
- (3) A summary of the project or study plan, including a project timeline, definition of project scope, and justification for the particular fields and records necessary for the project or study.
- (4) Signed data use agreement pursuant to present law by the requesting entity and any subcontractors.
- (5) Affirmation that the data requesting entity shall destroy all data in its entirety upon completion of the research project.

<u>Proposed law</u> provides the department shall enter into a data use agreement outlining the permitted uses and disclosures of the de-identified personal health information. The agreement shall include at a minimum the following:

- (1) A description of the requesting entity, including its ownership structure.
- (2) Rationale for the study or data use.
- (3) A summary of the project or study plan, including a project timeline, definition of project scope, and justification for the particular fields and records necessary for the project or study.
- (4) Identify all parties who may use or receive the information and prohibit any recipient from using or further disclosing the data, except as permitted by the agreement.
- (5) Include an affirmation that data shall be used only for the stated purpose, and that no attempts shall be made to combine data provided for in the request with other data to identify confidential information.
- (6) Require the recipient to use and demonstrate that appropriate safeguards are in place to prevent the use or disclosure of data that is not permitted by the agreement.
- (7) Require the recipient to report to the department any unauthorized use or disclosure of data.
- (8) Require the recipient to ensure that any agents, including subcontractors to whom it provides the information, agree to the data use restrictions.
- (9) Detail the method by which the data will be destroyed after the qualifying research project is completed.
- (10) Signed by the requesting health care research entity and any subcontractors. Any

future subcontractors shall be disclosed and approved by the department.

(11) Prohibit the recipient from identifying the information or contacting the individuals.

Effective August 1, 2014.

(Amends R.S. 40:1300.111-1300.114; adds R.S. 40:1300.115 and 1300.116)