Regular Session, 2014

HOUSE BILL NO. 350

BY REPRESENTATIVE STUART BISHOP

HEALTH CARE: Adds conditions and protections relative to use of patient healthcare data to the La. Health Care Consumers' Right to Know law

AN ACT

To amend and reenact R.S. 40:1300.111 through 1300.114 and to enact R.S. 40:1300.115 through 1300.117, relative to access to patient health care data; to provide findings and definitions; to provide relative to personal health information maintained within the Department of Health and Hospitals; to provide for data security protocols; to provide for duties of the Department of Health and Hospitals and of the Health Data Panel created therein; to provide conditions for the release of personal health information; to provide conditions for disclosure of health data for research purposes; to provide requirements for data use agreements; to provide for restrictions on uses of health data; 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 through 1300.117 are hereby enacted to read as follows:

§1300.111. Findings

The legislature hereby finds all of the following:

(1) As ~~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, 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 circumstances.

(2) Due to the rapidly expanding availability of and access to patient sensitive health care data, it is necessary to establish safeguards which ensure the level of protection of patient encounter data that Louisiana citizens deserve, and which protect the privacy of health information comprising data sets that are reported and disseminated for use in research endeavors intended to improve the population health of this state.

§1300.112. Definitions

As used in this Part, the following terms have the meaning ascribed to them in this Section:

(1) "Department" means the Department of Health and Hospitals.

(2) "HIPAA" means the Health Insurance Portability and Accountability Act, Pub. L. 104-191.

(3) "Secretary" means the secretary of the Department of Health and Hospitals.

~~§1300.112~~ §1300.113. Data collection; powers and duties of the Department of Health and Hospitals

A. The ~~Department of Health and Hospitals~~ department, 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~~ department in accordance with existing national and international data standards for ~~consumers'~~ facilitating meaningful comparison by consumers 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~~ HIPAA privacy regulations, ~~42~~ 45 CFR Part 164.

(6) Maintain the computerized database of personal health information of consumers in a secure environment in compliance with federal laws providing for the security of the system containing such data. In the event of a known or suspected data breach, the department shall, within thirty days of the breach, notify each resident of the state whose personal information was, or is reasonably believed to have been, acquired by an unauthorized person.

(7) Coordinate with the Louisiana Department of Insurance on all matters of health plan cost, quality, and performance data to be collected from health plans licensed to offer health insurance coverage in Louisiana. Such data shall exclude premium data and information related to the development of premiums.

~~(7)~~(8) Include appropriate risk-adjustment measures into the production of all health care cost, quality, and performance data issued to account for variation in facility size, location, and patient acuity levels.

~~(8)~~(9) Provide the process for Internet publication of provider and health plan specific cost, quality, and performance data collected pursuant to this Part for access and use by a consumer or requesting entity.

~~(9)~~(10) Ensure that data released pursuant to this Part shall not include any identifier which is listed in 45 CFR 164.514(b) as being necessary to be removed in order for the data to be de-identified within the meaning of 45 CFR 164.514(a).

~~(10)~~(11) Promulgate rules and regulations, in accordance with the Administrative Procedure Act, to carry out the provisions of this Part.

~~(11) Implement the initial phase of the Internet website created pursuant to this Part on or before April 30, 2009.~~

~~(12)~~ B. In the event that sufficient funds are not appropriated to implement this Part, to include the collection, storage, analysis, and dissemination of data to participating agencies, organizations, and the general public, the application and enforcement of this Part shall be suspended pending the appropriation of sufficient funds, and all accumulated health care data shall be stored with appropriate confidentiality safeguards, destroyed, or transferred to another appropriate agency or organization in accordance with state law.

~~§1300.113~~ §1300.114. Health Data Panel; advisory council to the secretary of the Department of Health and Hospitals

A. The ~~Department of Health and Hospitals~~ department shall create the Health Data Panel. The purpose of the Health Data Panel shall be to make recommendations to the secretary ~~of the Department of Health and Hospitals~~ for the implementation of the requirements of this Part. ~~The Health Data Panel shall consider the provisions set forth in R.S. 40:1300.112.~~

B. 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. 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.

C. The Health Data Panel shall consider the provisions set forth in R.S. 40:1300.113. Changes to the mandatory health care data elements or the methodology by which data is to 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 the department through rulemaking in accordance with the Administrative Procedure Act.

D. 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 this Part. The secretary ~~may~~ shall use the recommendations of the Health Data Panel to fulfill the ~~Department of Health and Hospitals'~~ responsibilities of the department as set forth in this Part.

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

§1300.115. Release of information

A. To ensure the privacy and protection of Louisianians' health information, the department shall ensure confidentiality of patient data collected from hospitals and other health care providers by adhering to and complying fully with appropriate privacy protection protocols that are at least as stringent as the HIPAA Privacy Rule. The department shall not release to any party outside of the department or any subcontractor of such party any of the following information collected pursuant to the provisions of this Part:

(1) Patient level data.

(2) Information collected from a health care provider that identifies a patient or person under whom the patient is insured.

(3) Any physician, facility, payer, or employer identifiers associated with the information provided for in Paragraphs (1) and (2) of this Subsection.

B. Notwithstanding any other provision of the law to the contrary, data collected pursuant to this Part may be disclosed for research purposes, but only under the following circumstances:

(1) The requesting entity is recognized as a health care research organization, focused on the improvement of health care outcomes through education and community engagement.

(2) The data sought for use in research qualifies as a de-identified personal health information as defined in the HIPAA Privacy Rule, 45 CFR 164.514.

C. All requests for data collected pursuant to the provisions of this Part shall be submitted to the department and reviewed and approved by a majority vote of the Health Data Panel. Each data request shall include 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 that includes a project timeline, definition of project scope, and justification for the particular fields and records necessary for the project or study.

(4) A data use agreement that conforms with all of the requirements of R.S. 40:1300.116 and is signed by a representative of the requesting entity and by representatives of any contractors of the entity.

(5) Affirmation that the entity requesting data will destroy the data in its entirety upon completion of the research project.

§1300.116. Data use agreement

A. The department shall enter into a data use agreement outlining the permitted uses and disclosures of de-identified personal health information. The agreement shall, at a minimum, include all of 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) Identification of all parties who may use or receive the information and affirmative acknowledgment of understanding that any recipient is prohibited from using or further disclosing the data, except as permitted by the agreement.

(5) An affirmation by the recipient of all of the following:

(a) That data will be used only for the purpose or purposes stated.

(b) That no attempts will be made to combine data provided for in the request with other data to identify confidential information.

(c) That the recipient will not derive the identity of any person whose information is contained in the data for the purpose of contacting any individual, or for any other purpose.

(6) Provisions explicitly requiring all of the following:

(a) That the recipient will use appropriate safeguards to prevent the use or disclosure of data that is not permitted by the agreement, and be able to demonstrate that such safeguards are in place.

(b) That the recipient report to the department any unauthorized use or disclosure of data.

(c) That the recipient ensure that any agents, including contractors and subcontractors to whom it provides the information, agree to the data use restrictions.

(7) Detail of the method by which the data will be destroyed after the qualifying research project is completed.

(8) The signature of an authorized representative of the requesting health care research entity and the signatures of authorized representatives of any subcontractors.

B. If after the execution of a data use agreement the recipient seeks to contract with any entity not identified in the agreement, the recipient shall disclose to the department the prospective contractor, and the contractual arrangement shall be subject to approval by the department.

~~§1300.114~~ §1300.117. Violations; penalties

A. All state agencies and health professional licensing, certification, or registration boards and commissions, which collect, maintain, or distribute health data, shall provide to the ~~Department of Health and Hospitals~~ department 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~~ department 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~~ department.

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)]

Stuart Bishop HB No. 350

Abstract: Adds conditions and protections relative to use of patient health care data to the La. Health Care Consumers' Right to Know law.

Present law, the La. Health Care Consumers' Right to Know (R.S. 40:1300.111 et seq.), provides relative to access to provider specific health care cost, quality, and outcome data on health care facilities, providers, and insurance plans. Proposed law generally retains present law and adds thereto certain conditions and restrictions for use of health care information.

Proposed law requires the Dept. of Health and Hospitals (DHH), in consultation with the Health Data Panel created as an advisory council within the department by present law, to maintain a computerized database of personal health information of consumers in a secure environment in compliance with federal laws providing for the security of the system containing such data. Requires that in the event of a known or suspected data breach, DHH shall, within 30 days of the breach, notify each La. resident whose personal information was, or is reasonably believed to have been, acquired by an unauthorized person.

Proposed law requires that changes to the mandatory health care data elements or the methodology by which data is to be reported by health care providers and health plans to DHH be approved by a majority vote of the members of the Health Data Panel and promulgated by DHH in rule.

Proposed law requires DHH to ensure confidentiality of patient data collected from hospitals and other health care providers by adhering to and complying fully with appropriate privacy protection protocols that are at least as stringent as the HIPAA Privacy Rule. Provides that DHH shall not release to any party outside of the department or any subcontractor of such party any of the following information collected pursuant to the provisions of proposed law:

(1) Patient level data.

(2) Information collected from a health care provider that identifies a patient or person under whom the patient is insured.

(3) Any physician, facility, payer, or employer identifiers associated with (1) or (2) above.

Proposed law provides that data collected pursuant to present law and proposed law may be disclosed for research purposes, but only under the following circumstances:

(1) The requesting entity is recognized as a health care research organization, focused on the improvement of health care outcomes through education and community engagement.

(2) The data sought for use in research qualifies as a de-identified personal health information as defined in the HIPAA Privacy Rule.

Proposed law provides that all requests for data collected pursuant to proposed law shall be submitted to DHH and reviewed and approved by a majority vote of the Health Data Panel. Requires that each data request 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 that includes a project timeline, definition of project scope, and justification for the particular fields and records necessary for the project or study.

(4) A data use agreement that conforms with all of the requirements of proposed law and is signed by a representative of the requesting entity and by representatives of any contractors of the entity.

(5) Affirmation that the entity requesting data will destroy the data in its entirety upon completion of the research project.

Proposed law requires DHH to enter into a data use agreement outlining the permitted uses and disclosures of de-identified personal health information. The agreement shall, at a minimum, include all of 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) Identification of all parties who may use or receive the information and affirmative acknowledgment of understanding that any recipient is prohibited from using or further disclosing the data, except as permitted by the agreement.

(5) An affirmation by the recipient of all of the following:

(a) That data will be used only for the purpose or purposes stated.

(b) That no attempts will be made to combine data provided for in the request with other data to identify confidential information.

(c) That the recipient will not derive the identity of any person whose information is contained in the data for the purpose of contacting any individual, or for any other purpose.

(6) Provisions explicitly requiring all of the following:

(a) That the recipient will use appropriate safeguards to prevent the use or disclosure of data that is not permitted by the agreement, and be able to demonstrate that such safeguards are in place.

(b) That the recipient report to DHH any unauthorized use or disclosure of data.

(c) That the recipient ensure that any agents, including contractors and subcontractors to whom it provides the information, agree to the data use restrictions.

(7) Detail of the method by which the data will be destroyed after the qualifying research project is completed.

(8) The signature of an authorized representative of the requesting health care research entity and the signatures of authorized representatives of any subcontractors.

Proposed law provides that after the execution of a data use agreement, if the recipient seeks to contract with any entity not identified in the agreement, then the recipient shall disclose to DHH the prospective subcontractor and the contractual arrangement shall be subject to approval by DHH.

(Amends R.S. 40:1300.111-1300.114; Adds R.S. 40:1300.115-1300.117)

Summary of Amendments Adopted by House

House Floor Amendments to the engrossed bill.

1. In proposed law relative to release of patient and provider data, specified that DHH shall not release such data to any party outside of the department or any subcontractor of an outside party.

2. In proposed law prohibiting DHH from releasing physician, facility, payer, or employer identifiers, specified that the prohibition applies to that information when it is associated with certain patient data that DHH is also prohibited from releasing pursuant to proposed law.

3. In proposed law requiring that requests for data be submitted to DHH, specified that the data to which this requirement applies is data collected by DHH pursuant to proposed law.

4. Made technical changes.