

2017 Regular Session

HOUSE BILL NO. 483

BY REPRESENTATIVES JACKSON, BAGNERIS, BILLIOT, BOUIE, TERRY BROWN, COX, GISCLAIR, JIMMY HARRIS, HUNTER, JEFFERSON, JENKINS, JOHNSON, JORDAN, LEBAS, LYONS, MARCELLE, NORTON, PIERRE, POPE, RICHARD, SMITH, AND STAGNI

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

HEALTH/CANCER: Provides relative to disclosure of data maintained by the Louisiana Tumor Registry and for a cancer investigation initiative

1 AN ACT

2 To amend and reenact R.S. 40:1105.10(B) and to enact R.S. 40:5.12, 1105.8.1, and 1105.8.2,

3 relative to collection, maintenance, and reporting of data on cancer by the Louisiana

4 Tumor Registry of the Louisiana State University System; to provide authorizations

5 and restrictions concerning reporting of data by the registry; to provide relative to

6 requests for registry data by the office of public health of the Louisiana Department

7 of Health; to provide for cooperation between the registry and the office of public

8 health in certain functions; to provide for state cancer investigation and intervention

9 functions; to establish procedures for processing of data requests submitted to the

10 registry; to provide for duties of the research committee of the registry; to provide

11 standards for the data collection process of the registry and for maintenance of data

12 collected; to provide for annual reports of cancer data to designated parties; to

13 provide for electronic notifications and reports concerning cancer data; and to

14 provide for related matters.

15 Be it enacted by the Legislature of Louisiana:

16 Section 1. R.S. 40:1105.10(B) is hereby amended and reenacted and R.S. 40:5.12,

17 1105.8.1, and 1105.8.2 are hereby enacted to read as follows:

1 concerning a patient, if requested, to a physician or medical facility diagnosing or
2 treating the case as authorized pursuant to 45 CFR 164.506.

3 B.(1) The tumor registry shall collaborate with the National Cancer Institute,
4 the Centers for Disease Control and Prevention, the North American Association of
5 Central Cancer Registries, the International Agency for Research on Cancer, and any
6 other national or international cancer surveillance program it may designate in
7 providing cancer data and participating in cancer studies.

8 (2) The tumor registry shall cooperate with the office of public health of the
9 Louisiana Department of Health, referred to hereafter in this Section as the "office
10 of public health", in evaluating programs and investigating cancer concerns and other
11 cancer-related issues through activities including, without limitation, cooperating
12 with the office of public health in implementing the program of cancer investigation
13 and intervention provided for in R.S. 40:5.12. Because the tumor registry data are
14 an integral part of national and state cancer prevention and control programs, the use
15 of registry data by office of public health officials and registry-designated national
16 cancer surveillance programs shall be considered an in-house activity and shall be
17 processed expeditiously.

18 (3) Requests by the office of public health for case-specific data shall require
19 annual approval by the office of public health institutional review board and by the
20 institutional review board of the Louisiana State University Health Sciences
21 Center-New Orleans, referred to hereafter in this Section as the "LSUHSC-New
22 Orleans". Additionally, the office of public health shall comply with all applicable
23 confidentiality standards of the tumor registry, and the tumor registry shall review
24 reports written for public release using tumor registry data in advance of their public
25 release.

26 C.(1) Subject to the limitations of Subsection F of this Section, the tumor
27 registry shall release case-specific data to persons or organizations for the purposes
28 of cancer prevention, control, and research in accordance with Paragraph (2) of this
29 Subsection. However, no such data shall include information collected for special

1 studies or other research projects. The tumor registry shall have and shall reserve the
2 right to prioritize its responses to data requests.

3 (2) Requests from persons or organizations for case-specific tumor registry
4 incidence data, including data linkages, shall be submitted in writing and shall be
5 reviewed and approved by the tumor registry research committee following the
6 established policies of the registry. These policies shall require, without limitation,
7 all of the following:

8 (a) Approval from the LSUHSC-New Orleans institutional review board and
9 compliance with the LSUHSC-New Orleans HIPAA research policy.

10 (b) Approval from the researcher's institutional review board and compliance
11 with that institution's HIPAA research policy.

12 (c) Execution of the tumor registry's form entitled "Agreement to Maintain
13 Confidentiality of Data", or any successor form, by each investigator who will have
14 access to the data indicating agreement by the investigator to adhere to the tumor
15 registry confidentiality provisions and prohibiting the disclosure of tumor registry
16 data in any civil, criminal, administrative, or other proceeding.

17 (d) Provision of a copy of the complete protocol for the project.

18 (e) Completion of all requirements provided in the document entitled
19 "Louisiana Tumor Registry: Researchers' Requests for Data", or any successor
20 document.

21 (f) Prior to contacting a patient or his next of kin, notification to the patient's
22 physician, if required.

23 (g) Destruction or return of data once the research is completed.

24 (3) If a request for data submitted in accordance with the provisions of this
25 Subsection is denied by the LSUHSC-New Orleans institutional review board, the
26 institutional review board shall provide to the requestor notice in writing of the
27 reason for the denial electronically or by postal mail.

1 D.(1) The director of the tumor registry or his designee shall coordinate the
2 research committee of the tumor registry. The research committee shall include,
3 without limitation, the following members:

4 (a) The director of the tumor registry.

5 (b) A qualified representative selected from each of the following entities:

6 (i) The LSUHSC-New Orleans.

7 (ii) The office of public health.

8 (iii) The Louisiana Cancer and Lung Trust Fund Board.

9 (2) The research committee shall verify that the researchers are able to
10 execute the proposal, in terms of both financial support and professional
11 qualifications; that the study has scientific and ethical merit; and that the researchers
12 will obtain appropriate consent.

13 E.(1) In determining the order of processing requests for data, the tumor
14 registry shall give priority to requests for data from the office of public health for use
15 in responding to concerns about threats to the public health.

16 (2) Subject to the provisions of the Public Records Law, R.S. 44:1 et seq.,
17 the tumor registry shall process requests for aggregate data other than those provided
18 for in Paragraph (1) of this Subsection in the order of receipt. The tumor registry
19 shall respond to any public request in a timely manner, as resources permit, if the
20 request meets the applicable requirements of R.S. 40:3.1 and 1105.8.

21 (3) The tumor registry may assess a charge to a requestor of data for actual
22 costs of compiling and providing the data, and may require payment before
23 proceeding to fulfill the data request.

24 (4) The tumor registry shall not be required in any instance to perform
25 original work to create data not currently in existence.

26 F.(1) The tumor registry shall not release data in cases in which such data
27 would disclose the identity of any person to whom the data relate and thus violate the
28 requirements of the Health Insurance Portability and Accountability Act relating to
29 uses and disclosure of protected health information (45 CFR 164.514). In such

1 situations, the tumor registry may combine more years of cancer data together at the
2 census tract level or suppress the data according to the suppression rule of the United
3 States Cancer Statistics program.

4 (2) In considering for approval or denial a request for aggregate data, the
5 research committee of the tumor registry shall determine whether the request
6 complies with applicable state and federal laws relating to privacy of health
7 information. If the research committee finds that disclosure of data in response to
8 the request would violate any such law, then the committee shall collaborate with the
9 requestor to revise the request in order to preclude such violation.

10 (3) In collaborating with a requestor as provided in Paragraph (2) of this
11 Subsection, the research committee shall employ methods for de-identifying
12 case-specific data as defined by the Centers for Disease Control and Prevention and
13 any other de-identification or statistical methods for disclosure protection.

14 (4) The research committee of the tumor registry shall not deny any request
15 for aggregate data for any reason that is unrelated to compliance with state or federal
16 privacy laws.

17 G. The tumor registry shall annually prepare a statistical report concerning
18 cancer rates and counts which includes data at the census tract level, and shall submit
19 the report to the office of the president for inclusion with the annual cancer report
20 required by R.S. 40:1105.10. The tumor registry shall also provide the statistical
21 report required by this Subsection to the Louisiana State University Health Sciences
22 Center at New Orleans, the Louisiana State University Health Sciences Center at
23 Shreveport, the Louisiana Cancer and Lung Trust Fund Board, and each participating
24 hospital.

25 §1105.8.2. Cancer data; electronic notifications and reports

26 The Louisiana Tumor Registry shall develop and publish on its website a
27 mechanism by which individuals may elect to receive in electronic format
28 notifications and reports issued by the tumor registry.

29 * * *

1 §1105.10. Annual cancer report

2 * * *

3 B. The ~~report office of the president~~ shall cause the report to be submitted
4 by March 31 ~~thirty-first~~ of each year to the governor, the speaker of the House of
5 Representatives, the president of the Senate, ~~and the House and Senate Committees~~
6 committees on Health and Welfare ~~health and welfare~~, and the governing body of
7 each parish in the state of Louisiana.

8 * * *

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 483 Reengrossed

2017 Regular Session

Jackson

Abstract: Provides relative to disclosure of data maintained by the La. Tumor Registry, for duties of the registry's research committee, and for a cancer investigation and intervention program.

Proposed law requires the La. Tumor Registry (tumor registry) to provide diagnostic, treatment, and follow-up information concerning a patient at the request of a physician or medical facility diagnosing or treating the case as authorized by federal regulations relative to privacy of health information (45 CFR 164.506).

Proposed law requires the tumor registry to collaborate with the National Cancer Institute, the Centers for Disease Control and Prevention, the North American Association of Central Cancer Registries, the International Agency for Research on Cancer, and any other national or international cancer surveillance program it may designate in providing cancer data and participating in cancer studies.

Proposed law requires the tumor registry to cooperate with the office of public health of the La. Department of Health (OPH) in all of the following:

- (1) Evaluating programs.
- (2) Investigating cancer concerns and other cancer-related issues.
- (3) Implementing the program of cancer investigation and intervention provided for in proposed law.

Proposed law provides that the use of registry data by OPH officials and registry-designated national cancer surveillance programs shall be considered an in-house activity and be processed expeditiously.

Proposed law provides that requests by OPH for case-specific data shall require annual approval by the institutional review boards of OPH and the La. State University Health Sciences Center-New Orleans (LSUHSC-New Orleans). Requires compliance by OPH with confidentiality standards of the tumor registry.

Proposed law requires that, subject to the limitations of federal law and proposed law relative to privacy of health information, the tumor registry shall release case-specific data to persons or organizations for the purposes of cancer prevention, control, and research; but prohibits inclusion in such data of information collected for special studies or other research projects. Requires requests for such data to be submitted in writing and reviewed and approved by the tumor registry research committee.

Proposed law provides that if a request for data submitted in accordance with proposed law is denied by the LSUHSC-New Orleans institutional review board, the institutional review board shall provide to the requestor notice in writing of the reason for the denial electronically or by postal mail.

Proposed law requires the director of the tumor registry or his designee to coordinate the registry's research committee. Provides that the research committee shall include, without limitation, the following members:

- (1) The director of the tumor registry.
- (2) A qualified representative selected from each of the following entities:
 - (a) The LSUHSC-New Orleans.
 - (b) OPH.
 - (c) The La. Cancer and Lung Trust Fund Board.

Proposed law provides for duties of the research committee with respect to requests for tumor registry data.

Proposed law requires that in determining the order of processing requests for data, the tumor registry shall give priority to requests for data from OPH for use in responding to concerns about threats to the public health. Provides that the registry shall process other requests for data in order of receipt, and that the registry may seek reimbursement from a requestor for actual costs of compiling and providing the data.

Proposed law provides standards for the tumor registry's data collection process and for maintenance by the registry of data collected. Authorizes the tumor registry to assess a charge to a requestor of data for actual costs of compiling and providing the data, and to require payment before proceeding to fulfill the data request.

Proposed law prohibits the tumor registry from releasing data in cases in which such data would disclose the identity of any person to whom the data relate and thus violate the requirements of the Health Insurance Portability and Accountability Act relating to uses and disclosure of protected health information (45 CFR 164.514). Provides that in such situations, the tumor registry may combine more years of cancer data together at the census tract level or suppress the data according to the suppression rule of the United States Cancer Statistics program.

Proposed law provides that in considering for approval a request for aggregate data, the research committee of the tumor registry shall determine whether the request complies with applicable state and federal laws relating to privacy of health information. Provides that if the research committee finds that disclosure of data in response to the request would violate any such law, then the committee shall collaborate with the requestor to revise the request in order to preclude such violation.

Proposed law prohibits the research committee of the tumor registry from denying any request for aggregate data for any reason that is unrelated to compliance with state or federal privacy laws.

Proposed law requires the tumor registry to prepare an annual statistical report concerning cancer rates and counts which includes data at the census tract level, and to submit the report to the office of the president of the LSU System for inclusion with the annual cancer report provided for in present law (R.S. 40:1105.10). Provides that the tumor registry shall also submit the statistical report to the following entities:

- (1) The La. State University Health Sciences Center at New Orleans.
- (2) The La. State University Health Sciences Center at Shreveport.
- (3) The La. Cancer and Lung Trust Fund Board.
- (4) Each participating hospital.

Present law (R.S. 40:1105.10) requires that an annual cancer report be developed by the LSU System and issued to the governor, the speaker of the House of Representatives, the president of the Senate, and the legislative committees on health and welfare. Proposed law requires that this report also be transmitted to the governing body of each parish in the state.

Proposed law requires the tumor registry to develop and publish on its website a mechanism by which individuals may elect to receive in electronic format notifications and reports.

Proposed law grants OPH legislative authority to operate a program of cancer investigation and intervention if sufficient funding is available for this purpose. Provides that the source of monies for the program may be any appropriation by the legislature, including appropriations of federal funds; appropriations from the Health Excellence Fund and the La. Fund created by present constitution; any public or private donations, gifts, or grants from individuals, corporations, nonprofit organizations, or other business entities; and any other monies which may be provided by law.

Proposed law requires OPH to engage and collaborate with the tumor registry, the La. Cancer Research Center, and the La. Advisory Committee on Populations and Geographic Regions With Excessive Cancer Rates in administering the cancer investigation and intervention program provided for in proposed law. Stipulates that the program shall be conducted in addition to the activities of, and shall not replace or supplant, the Breast Cancer Control Program provided for in present law (R.S. 40:1105.13).

(Amends R.S. 40:1105.10(B); Adds R.S. 40:5.12, 1105.8.1, and 1105.8.2)

Summary of Amendments Adopted by House

The Committee Amendments Proposed by House Committee on Health and Welfare to the original bill:

1. Grant the office of public health (OPH) legislative authority to operate a cancer investigation and prevention program, subject to availability of funds for this purpose.
2. Provide that the source of monies for the cancer investigation and prevention program may be from any lawful source.
3. Stipulate that OPH shall engage and collaborate with the La. Tumor Registry (tumor registry) and the La. Advisory Committee on Populations and Geographic Regions With Excessive Cancer Rates in administering the cancer investigation and prevention program.

4. Provide that the cancer investigation and prevention program shall be conducted in addition to the activities of, and shall not replace or supplant, the Breast Cancer Control Program provided for in present law.
5. Authorize the tumor registry to release aggregate data for geographic areas smaller than the zip code and census tract level if requested by any of the following parties:
 - (a) An elected member of the Legislature of La.
 - (b) An elected official serving in the executive branch of state government.
 - (c) The secretary of a department of the executive branch of state government.
6. Require the tumor registry to develop and publish on its website a mechanism by which individuals may elect to receive in electronic format notifications and reports.
7. Require that the annual cancer report issued pursuant to present law by the president of the LSU System to the governor, the speaker of the House of Representatives, the president of the Senate, and the legislative committees on health and welfare also be transmitted to the governing body of each parish in the state.
8. Make technical changes.

The House Floor Amendments to the engrossed bill:

1. Change the description of a program provided for in proposed law ~~from~~ a cancer investigation and prevention program to a cancer investigation and intervention program.
2. Add the La. Cancer Research Center as an entity with which the office of public health shall collaborate in administering the cancer investigation and intervention program provided for in proposed law.
3. Delete proposed law requiring that reports published or presented by the La. Tumor Registry (tumor registry) shall include aggregate, not case-specific, data.
4. Revise proposed law prohibiting disclosure by the tumor registry of information that would potentially identify a patient to specify that the tumor registry shall not release data in cases in which such data would disclose the identity of any person to whom the data relate and thus and thus violate requirements of the Health Insurance Portability and Accountability Act.
5. Delete proposed law requiring that persons or organizations to whom the tumor registry may release case-specific data in certain circumstances must be qualified persons or organizations.
6. Require that if a request for data submitted in accordance with the provisions of proposed law is denied by the LSU Health Sciences Center-New Orleans institutional review board, the institutional review board shall provide to the requestor notice in writing of the reason for the denial.
7. Revise proposed law authorizing the tumor registry to seek reimbursement for costs of compiling and providing data to provide that the tumor registry may

assess a charge to a requestor of data for actual costs of compiling and providing the data, and may require payment before proceeding to fulfill the data request.

8. Delete proposed law providing all of the following:
 - (a) That the tumor registry shall make available to the public information concerning its costs of compiling and providing data.
 - (b) That the zip code and census tract are the smallest geographic areas for which the tumor registry may release aggregate data.
 - (c) That the tumor registry may release aggregate data for geographic areas smaller than the zip code and census tract if requested by a state legislator, an elected executive branch official, or the secretary of a department of the executive branch.
 - (d) That as part of the data collection process, the tumor registry shall collect demographic and geographic data as reportable, separated variables.
 - (e) That the tumor registry shall maintain data in such a manner that the data may be retrieved from tumor registry computer systems without necessity of creating new tabulations, programs, records, or reports.
 - (f) That the tumor registry shall maintain data in a manner which facilitates provision of data in response to requests for aggregate data and extraction by a simple query of the specific data fields.
 - (g) A listing of specific statistical methods which the tumor registry may employ in de-identifying data for purposes of disclosure protection.
9. Delete proposed law providing that the tumor registry may be obligated to extract existing data collected as independent variables.
10. Delete proposed law requiring the tumor registry to prepare an annual statistical report concerning disclosure of data to qualified persons and organizations.
11. Add proposed law requiring the tumor registry to prepare an annual statistical report concerning cancer rates and counts which includes data at the census tract level.