Birth Defects Surveillance System

<table>
<thead>
<tr>
<th>State</th>
<th>Statute/Rule</th>
<th>Language Specific to Surveillance System</th>
<th>Data Sharing</th>
<th>Research Authority</th>
<th>Consent Required?</th>
<th>Dissent Allowed?</th>
</tr>
</thead>
<tbody>
<tr>
<td>LA</td>
<td>STATUTE: RS 40:31.41 Part VII. RULE: LAC 48: V. Chapters 161 and 163. §31.43. Louisiana Birth Defects Surveillance System A. The department shall establish a birth defects surveillance system within the office of public health to collect, analyze, interpret, and disseminate data relative to birth defects in Louisiana. B. In establishing the surveillance system, the department shall require reporting sources to report information on birth defects to the office. However, reporting sources shall not collect or report information on birth defects of a child to the office whenever there is a written objection by the parent or legal guardian that collecting and reporting such information would conflict with their religious tenets or practices. §31.44. Confidentiality. Notwithstanding any other provision of the law to the contrary, individual identifying data in the surveillance system shall be confidential and shall not be subject to discovery. Such data shall not be released unless express written informed consent of a parent or legal guardian has been obtained. Data gathered by the office shall be used only for the purposes set forth in this Part. §16307. Access to Information from the Central Registry. A. The LBDMN or other authorized persons may conduct investigations of cases of suspected cases in the LBDMN registry. B. Access to the central registry information is limited to LBDMN personnel. Other persons with a valid scientific research interest may be granted access to the information upon approval by program director, the board, and the Department’s Institutional Review Board… Title 48 PUBLIC HEALTH—GENERAL. Part I. General Administration Chapter 5. Disclosure of Confidential Information §501. General Provisions B. It is the policy of the department to protect, to the fullest extent possible, the privacy of individuals, while permitting the disclosure of confidential information as is required to fulfill the administrative responsibilities of the department, to further scientific research, and to assist the patient/client. C. These rules apply to every agency within the department which maintains or makes use of medical or confidential information concerning individuals. If an agency is governed by federal regulations which provide stricter standards or confidentiality, these rules shall be deemed superseded by the federal regulations, to the extent that they are in conflict with the federal regulations.</td>
<td>NO</td>
<td>YES</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### §16303. Reporting Requirements

A. The office shall determine the health care facilities and providers which shall be required to report all birth defects, the types of conditions or defects that shall be reported, the type of information that shall be contained in the confidential report and the method for making the report. …

7/26/08: BD Registry “is planned” - [http://www.dhh.state.la.us/offices/7ID–261](http://www.dhh.state.la.us/offices/7ID–261) (“Over the next several years, we plan to implement full statewide active surveillance for birth defects, and generate an annual report of surveillance activities and findings.”)

---

### §509. Disclosures Without the Patient's Consent

C. Disclosures to Qualified Personnel for the Purpose of Scientific Research, Statistical Compilation, Audit or Evaluation

1. Disclosure of medical information to qualified personnel is authorized without the consent of the patient, for the purposes of scientific research, statistical compilation, audit and evaluation when the information disclosed does not contain patient identifying information. …If the person compiling the scientific research, statistical analysis, audit or evaluation report believes that patient identifying information is essential to his compilation, he shall direct his request for information in writing to the secretary of the department. This request shall contain an explanation of the nature and purpose of the compilation and of the reason patient identifying information is deemed essential. The secretary shall review the request and shall authorize the disclosure of the medical information containing patient identifying information only if he determines that the value of the compilation outweighs the patient's right to privacy…

2. Upon receipt of the agreement of compliance, the secretary shall authorize the agencies involved to release the medical information. If the secretary determines that the value of the compilation does not outweigh the patient's right to privacy he may either deny the request or may authorize disclosure of the medical records with the patient identifying information deleted.
Title 48 PUBLIC HEALTH—GENERAL.
Part I. General Administration:

Chapter 5. Disclosure of Confidential Information

§505. Confidentiality and Disclosure

K. Refusal to Consent to Disclosure of Records. Except as otherwise provided in these rules, all patients have the right to refuse to consent to the disclosure of medical information concerning themselves and no agency shall refuse medical treatment to a patient solely because he refuses to consent to the disclosure of medical information about himself.
### Cancer Surveillance System

<table>
<thead>
<tr>
<th>State</th>
<th>Statute/Rule</th>
<th>Language Specific to Surveillance System</th>
<th>Data Sharing</th>
<th>Research Authority</th>
<th>Consent Required?</th>
</tr>
</thead>
<tbody>
<tr>
<td>LA</td>
<td>STATUTE: RS 40: 1299.80 to 1299.87 RULE: LAC 48:V.8501-8513</td>
<td>§1299.81. Cancer registry program; data; statewide</td>
<td>§1299.84. Participation in program</td>
<td>1299.87. Disclosure of medical records to cancer registries</td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The president of the Louisiana State University System shall establish in the office of the president a statewide registry program for reporting cancer cases for the purpose of gathering statistical data to aid in the assessment of cancer incidence, survival rates, possible causes of specific cancers, and other related aspects of cancer in Louisiana. The program shall collect and disseminate cancer incidence data on a statewide level in accordance with the provisions of this Part. §1299.82. Powers; duties. The president shall:</td>
<td>A. Any health care provider or radiation center diagnosing or providing treatment to cancer patients shall report each case of cancer to the president…</td>
<td>…C. The office of the president shall promulgate rules and regulations in accordance with the Administrative Procedure Act to specify the extent to which confidential data may be disclosed to other local, state, or federal public health or environmental agencies, or to corroborating medical researchers, when the confidential information is necessary to carry out the duties of the agency or researchers in the investigation, control, or surveillance of disease, as determined by the office of the president. Before releasing confidential information to the researchers, the president shall obtain an agreement in writing from the researchers that they will keep nonaggregate, case-specific information confidential and privileged and that neither the office of the president nor the other entity shall bear liability for loss, expense, attorney fees, or claims for injury or damages arising out of acts or omissions in the performance of this agreement on the part of the other.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(1) Collaborate with each participating health care provider and radiation center in the state of Louisiana to establish a uniform statewide registry system for collecting cancer incidence data and shall promulgate rules and regulations therefor in accordance with policies established by the board...</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(3) Cooperate with the National Cancer Institute, the Centers for Disease Control, and other national and international cancer surveillance programs designated by the Louisiana Tumor Registry in providing cancer data….</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(5) Collabrate in studies with clinicians and epidemiologists and publish reports on the results of such studies…[and]</td>
<td>B. The president may enter into agreements to exchange confidential information with other cancer registries in order to obtain complete reports of Louisiana residents diagnosed or treated in other states and to provide information to other states regarding their residents diagnosed or treated in Louisiana. E. The furnishing of confidential data in accordance with this Part shall not expose any person, agency, or entity furnishing data to liability and shall not be considered to be in violation of any privileged or confidential relationship…</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(8) Contract with private tumor registries for the collection and furnishing of data to the statewide registry and for the necessary planning and coordination incident thereto.</td>
<td>Tumor Registry (LAC 48:V.Chapter 85) §8503. Definitions Confidential Data Cshall include any information that pertains to an individual case, as ordinarily distinguished from group, aggregate, or tabular data. Statistical totals of &quot;0&quot; or &quot;1&quot; may be deemed confidential, case-specific data. Confidential, case-specific data include, but are not limited to, primary or potential human identifiers. In addition, in research involving data contained in the Centers for Disease Control's National Center for Health Statistics database, statistical totals of 5 or less are also deemed confidential data and are suppressed unless prior written consent of all of the affected respondents has been obtained…</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Newborn Genetic Testing & Surveillance System

<table>
<thead>
<tr>
<th>State</th>
<th>Statute/Rule</th>
<th>Language Specific to Surveillance System</th>
<th>Exemption</th>
<th>Research Authority</th>
</tr>
</thead>
<tbody>
<tr>
<td>LA</td>
<td>STATUTE: RS 40:1299 Part XV</td>
<td>PART XV. GENETIC CONDITIONS AND NEWBORNS: §1299. Programs for combating phenylketonuria, congenital hypothyroidism, galactosemia, sickle cell diseases, biotinidase deficiency, and other genetic conditions A. The Department of Health and Hospitals is hereby authorized and directed to establish, maintain, and carry out programs designed to reduce mortality and morbidity from sickle cell disease and to prevent central nervous system damage in children with phenylketonuria, congenital hypothyroidism, biotinidase deficiency, and genetic conditions tested under the authority of R.S. 40:1299.1(B). §1299.1. Tests A. (1) The physician attending a newborn child, or the person attending a newborn child who was not attended by a physician, shall cause the child to be subjected to tests... (2) If any of the tests are positive, the attending physician or person shall notify the Department of Health and Hospitals; (3) The department shall follow up all positive tests with the attending physician who notified the department thereof and with the parents of the newborn child... LAC 48: V 6303 (G)...8. Mandatory Reporting of Positive Test Results Indicating Disease...10. Reporting requirements of private laboratories to the Genetic Diseases Program Office for public health surveillance and quality assurance purposes. a. The laboratory must submit quarterly statistical reports to the Genetic Disease Program Office that indicate the number of specimens screened by method, the number of specimens unsatisfactory for testing, the number normal and positive, and for screening of hemoglobinopathies, the number by phenotype...</td>
<td>§1299.1. Tests A.1) The physician attending a newborn child, or the person attending a newborn child who was not attended by a physician, shall cause the child to be subjected to tests for phenylketonuria... and other genetic conditions that have been approved by the Department of Health and Hospitals; however, no such tests shall be given to any child whose parents object thereto.</td>
<td>$1299. ...B.1) The Department of Health and Hospitals shall establish and maintain a diagnostic laboratory for each of the following purposes: (a) Conducting experiments, projects, and other undertakings as may be necessary to develop tests for the early detection of phenylketonuria, congenital hypothyroidism, galactosemia, sickle cell diseases, biotinidase deficiency, and other genetic conditions. (b) Developing ways or discovering methods to be used for the prevention and treatment of these diseases. (c) Such other purposes as may be deemed necessary by the department to carry out any program adopted under the authority of this Part, including conducting experiments, projects, and other undertakings as may be necessary to develop tests for genetic conditions made part of the battery of tests by the Department of Health and Hospitals under R.S. 40:1299.1(B).</td>
</tr>
</tbody>
</table>
b. The laboratory must electronically report newborn screening results on all Louisiana newborns screened to the Genetic Diseases Program Office on a monthly basis. The file format and data layout will be determined by the Genetic Diseases Program. Essential patient data is the following and is required to be reported unless “optional” is indicated:

i. child’s first name;
ii. child’s last name;
iii. mother’s first name;
iv. mother’s last name;
v. mother’s maiden name (optional);
vi. child’s street address;
vii. child’s city;
viii. child’s state;
ix. child’s zip code;
x. child’s parish (optional);
xii. child’s date of birth (format: mm/dd/yyyy);
xii. child’s sex;
xiii. child’s race (format: (W)hite, (B)lack, Native America, Asian, other, Hispanic);
xiv. mother’s social security number (format: 999-99-9999);
xv. Child’s test results.

§1299.1. Tests. … B. The Department of Health and Hospitals shall, after consultation with medical geneticists from each of the state's medical schools and by rule adopted in accordance with the Administrative Procedure Act, add to the genetic conditions tested for in Subsection A of this Section; however, no approved test for any genetic condition added shall be given to any child whose parents object thereto.
## Vaccination Surveillance System

<table>
<thead>
<tr>
<th>State</th>
<th>Statute/Rule</th>
<th>Language Specific to Surveillance System</th>
<th>Exemption</th>
<th>Data Sharing</th>
<th>Consent Required?</th>
<th>Dissent Allowed?</th>
</tr>
</thead>
<tbody>
<tr>
<td>LA</td>
<td>STATUTE: RS 40: §31.13 RULE: NONE FOUND</td>
<td>§31.13. Development of immunization registry and tracking and recall system; standards</td>
<td>Q. Do I have to get consent from the parent to share the record with LINKS? &lt;br&gt; A. No. The state law authorizing the development of LINKS does not require you to obtain consent. The LINKS staff prepared posters and brochures to inform parents of the registry and why information is submitted to the registry. These are available from the LINKS website address <a href="https://linksweb.oph.dhh.louisiana.gov">https://linksweb.oph.dhh.louisiana.gov</a> or contact (504) 838-5300. State law requires you to use these signs or brochures to help inform parents. &lt;br&gt; Q. Can a parent get the child immunized and refuse to share the record with LINKS? &lt;br&gt; A. No. The parent can refuse to let their child’s information be shared with other providers, however. If the parent decides not to let their child’s information be shared, you can still report that information and you and the local health unit will still be able to view that information.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>§31.14. Authorization of release of immunization records</td>
<td>NO</td>
<td>NO</td>
<td></td>
</tr>
</tbody>
</table>

Taken from https://linksweb.oph.dhh.louisiana.gov/linksweb/LINKS_DCNTR.html

§31.16. Parental consent; parental responsibility for immunization; exemptions

A. (1) Nothing in this Part shall be construed to restrict the registry from providing tracking and recall information to the parent or guardian that provides the consent for the child to be entered into an immunization registry.

(2) General consent for treatment and release of information to other providers or to the office of public health shall be considered parental consent for sharing historical, current, and future immunization information. In addition, each immunization provider shall comply with at least one of the following requirements:

Copyright © Citizens’ Council for Health Freedom August 2013
Updated August 2012. All state statutes and department rules originally accessed online July/Aug 2008. Statute/Rule data not inclusive. For comprehensive or updated language, access complete statute and rules online, at local library or through the state legislature. www.cchfreedom.org
(9) Methods assuring that information contained in the immunization registry only be used to track and document immunization status, for other immunization program-related activities, and for associated public health research.

CONSENT WAS UNDONE IN 2002:

Links Update “LINKS continues to be a success!!! The Senate recently approved HB 91 which clears the language of the registry law, ends its confusing interpretation and strikes down the specific consent requirement. This is great news for populating LINKS!” - Shots for Tots Coalition Newsletter, Vol 1, Issue 2, 2002.

(9) Methods assuring that information contained in the immunization registry only be used to track and document immunization status, for other immunization program-related activities, and for associated public health research.

(9) Methods assuring that information contained in the immunization registry only be used to track and document immunization status, for other immunization program-related activities, and for associated public health research.

(a) Place a poster in the patient registration area notifying parents that the site is participating in the state immunization registry and that childhood data is being shared with the registry.

(b) Provide each parent a brochure supplied by the office of public health describing the purposes of the registry and notifying parents that they can prohibit data sharing by notifying the health care provider not to submit their child’s immunization information.

(3) In the event of a public health emergency as declared by the state health officer, including a natural disaster, bioterrorist attack, epidemic, or other event affecting the public health, the requirement to obtain consent for placement on a registry shall be waived for mass immunizations performed in response to such declaration.

B. The immunization record of a child shall be purged from the registry at any time that the child's custodial parent or legal guardian requests, in writing, that the immunization record be purged from the registry.

C. Nothing in this Part shall be construed to mitigate the responsibility of a parent or guardian to have a child of that parent or guardian properly immunized.

D. Nothing in this Part shall be construed to require immunization or tracking of any child otherwise exempt from immunization requirements for medical or religious reasons.

§31.14 (C) …Upon a client's attainment of twenty-one years of age, the client's immunization record and tracking and recall record shall be purged from the registry, except that non-identifying data may be retained for statistical analysis.

§31.15. Rulemaking

The Department of Health and Hospitals, office of public health, shall promulgate rules and regulations pertaining to the development and implementation of the immunization registries and their associated tracking and recall systems in accordance with the Administrative Procedure Act. The rules shall include a process by which a custodial parent or guardian can control the transfer of information from the immunization record or the immunization tracking and recall record when such control is necessary to protect the health or safety of the family.

B. A provider, a public health unit, the Department of Health and Hospitals, or the agents of any of them, schools, and day care centers shall not be subject to an action or be liable for sharing information from the immunization record or using information from the immunization tracking and recall record for purposes of tracking immunizations of clients and for outreach to clients who have missed immunizations.

C. Information in an immunization registry or in the immunization tracking and recall record or derived therefrom is confidential and shall not be disclosed to any person who is not specifically authorized to receive information under this Part.