

RULE**Department of Health and Hospitals
Office of Public Health****Birth Defects Surveillance System
(LAC 48:V.Chapters 161 and 163)**

In accordance with the applicable provision of the Administrative Procedure Act R.S. 49:950 et seq. and the Birth Defects Surveillance System R.S. 40.31.41 through 31.48 et seq., notice is hereby given that the Department of Health and Hospitals, Office of Public Health has adopted procedures for the surveillance of birth defects for all children under age 3, for provision of information on appropriate follow-up services to families of children identified as having birth defects, and for protection of the confidentiality of information about children who become part of the birth defects registry as well as the privacy of these individuals and their families.

Title 48**PUBLIC HEALTH ◊ GENERAL****Part V. Public Health Services****Subpart 55. Birth Defects Surveillance
System****Chapter 161. General Provisions****§16101. Definitions**

Advisory Board ◊ the nine-member advisory board of the program.

Birth Defect ◊ an abnormality of structure, function or metabolism that develops during prenatal, perinatal or early postnatal life that is diagnosed before a child reaches 3 years of age.

Case Finding ◊ the process used to identify potential birth defects cases for inclusion into the central registry or central database of the Louisiana Birth Defects Monitoring Network.

CSHS ◊ the Children's Special Health Services Program within the Office of Public Health.

Confidential Information ◊ information collected through the Louisiana Birth

Defects Monitoring Network that is private and protected under state and federal laws.

Director ◊ the program director for the Louisiana Birth Defects Monitoring Network.

Department ◊ the Department of Health and Hospitals.

LBDMN ◊ the Louisiana Birth Defects Monitoring Network, which the office will establish to collect information about children with birth defects. The LBDMN is established to carry out the directives of the Louisiana Birth Defects Surveillance System, which was created under Louisiana Revised Statutes 40.31.41-31.48.

Office ◊ the Office of Public Health within the Department of Health and Hospitals.

Registry ◊ the centralized database where data collected through the LBDMN is housed.

Reporting Source ◊ any physician, nurse or allied health professional, hospital, laboratory, and any other facility or agent directly or indirectly responsible for providing medical services to an individual affected by a birth defect.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40.31.48.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 30:1019 (May 2004).

Chapter 163. Program Procedures**§16301. Procedures for Identification and Referral of Children with Birth Defects**

A. The program will include the following.

1. Reporting sources required to report pursuant to the rule shall allow personnel from the department or its contractors to abstract information from the mother's and infant's files on their demographic characteristics, family history of birth defects, and outcomes of that and other pregnancies by that mother, according to the case definition used in LBDMN.

2. The chief operating officer, administrator, manager, director, and/or

person in charge of each reporting source shall appoint one staff member as a contact person for the LBDMN surveillance activities. That staff member should be responsible for coordinating scheduled visits by LBDMN staff to review logs, discharge indices, and other casefinding sources, and will be responsible for arranging medical records review visits and record management.

3. LBDMN staff and the contact individual at the reporting source shall establish a schedule of case-finding and record review visits. This schedule shall take into account the capabilities of each individual reporting source in responding to data/information requests, as well as the need for timely case-finding and reporting for the LBDMN.

4. Potential cases are obtained/abstracted through review of medical records, logs, indices, appointment rosters, and other records.

5. The original medical records and other materials provided by the reporting source shall not be removed from that facility. Copies and other data should be made in compliance with existing federal and state laws and regulations.

6. The office will require information from a reporting source to be collected on a birth defects reporting form. This may be an electronic or paper form, as determined by LBDMN procedures.

7. The office will maintain a centralized database to include information reported on the birth defects reporting form.

8. The office will notify parents of infants and children identified of available early intervention services in their community.

B. Implementation

1. All reporting sources must comply with Act 194 of 2001 and these rules by July 1, 2004.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40.31.48.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 30:1019 (May 2004).

§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.

B. To ensure an accurate source of data necessary to investigate the incidence, prevalence, and trends of birth defects, a reporting source shall make available to the program staff, office staff, or authorized agent medical records or other information upon request that relates to the occurrence of a birth defect.

C. The department secretary may require, in lieu of active case finding, reporting sources identifying and diagnosing birth defects to report the birth defects to the program within 30 days of diagnosis.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40.31.48.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 30:1020 (May 2004).

§16305. Confidentiality

A. Except as specifically authorized by this Chapter, information furnished to a LBDMN employee or to an authorized agent of the office that relates to cases or suspected cases of a birth defect is confidential and may be used only for the purposes outlined in this Chapter.

B. Information relating to individual cases or individual suspected cases of birth defects is not public information and shall not be released or made public except as provided by this Chapter.

C. The LBDMN may release information:

1. for summary reporting purposes, if released without personal identifiers;

2. to medical personnel, appropriate state agencies, health authorities, regional directors, and public officers of parishes and municipalities as necessary to comply with this Chapter and board rules relating to the identification, monitoring, and referral of children with birth defects;

3. to appropriate federal agencies, as authorized by law and provided that the information contains no personal identifiers.

D. No reporting source shall be held civilly or criminally liable for conveying confidential information, except in a case of gross negligence or willful misconduct.

E. A board member, the secretary of the department, an employee of the LBDMN or office, or an authorized agent may not be examined in a civil, criminal, special, or other proceeding as to the existence or contents of pertinent records of or reports or information about a child identified or monitored for a birth defect without the consent of the child's parents, managing conservator, guardian, or legally authorized representative.

F. All employees or authorized agents of the LBDMN or office given access to medical or registry records shall agree, in writing, to maintain confidentiality of information about children with birth defects and to protect the privacy of individuals and families who become part of the LBDMN registry.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40.31.48.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 30:1020 (May 2004).

§16307. Access to Information from the Central Registry

A. The LBDMN or other authorized persons may conduct investigations of cases or 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. These persons must satisfy any requirements stipulated by the board, and must receive Institutional Review Board permission to obtain the data.

C. All persons granted access to confidential information and data shall agree, in writing, to maintain confidentiality, and shall be subject to civil penalties and/or

internal proceedings and penalties if confidentiality is violated. Penalties may include denial of future access to confidential information.

D. The department and LBDMN shall maintain a listing of each person who is given access to confidential information in the LBDMN registry. The listing is public information and shall be made available to the public during the office's normal hours of operation. The listing shall include:

1. the name of the person authorizing access;
2. the name, title, and organizational affiliation of each person who is granted access;
3. the dates of access;
4. the specific information requested;
5. the specific purpose for which the information was used;
6. results of independent research.

E. Progress reports and reports of findings generated from approved studies shall be submitted to the LBDMN staff and board annually or at the conclusion of the project, if the duration is shorter than 12 months.

F. All persons granted access to LBDMN information and data shall certify the destruction of data at the conclusion of the project.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40.31.48.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 30:1020 (May 2004).

§16309. Program Operation

A. The office shall monitor reporting sources for compliance with all sections of this statute.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40.31.48.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 30:1021 (May 2004).

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