

GENERAL ASSEMBLY OF NORTH CAROLINA

SESSION 1995

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SENATE BILL 818

Short Title: Birth Defects/Monitor.

(Public)

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Sponsors: Senators Speed, Forrester, Martin of Guilford, Carpenter, Allran, Dannelly, Soles, and Lucas.

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Referred to: Children and Human Resources

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April 25, 1995

1 A BILL TO BE ENTITLED  
2 AN ACT TO ESTABLISH A BIRTH DEFECTS MONITORING PROGRAM IN THE  
3 DEPARTMENT OF ENVIRONMENT, HEALTH, AND NATURAL RESOURCES.  
4 The General Assembly of North Carolina enacts:

5 Section 1. Article 5 of Chapter 130A of the General Statutes is amended by  
6 adding the following new Part to read:

7 **"PART 7. BIRTH DEFECTS.**

8 **"§ 130A-131.16. Birth defects monitoring program established; definitions.**

9 (a) The Birth Defects Monitoring Program is established within the State Center  
10 for Health and Environmental Statistics. The Birth Defects Monitoring Program shall  
11 compile, tabulate, and publish information related to the incidence and prevention of birth  
12 defects.

13 (b) As used in this Part, unless the context clearly requires otherwise, the term:

14 (1) 'Birth defect' means any physical, functional, or chemical abnormality  
15 present at birth that is of possible genetic or prenatal origin.

16 (2) 'Program' means the Birth Defects Monitoring Program established  
17 under this Part.

18 (b) Physicians and persons in charge of medical facilities shall, upon request,  
19 permit staff of the Program to examine, review, and obtain a copy of any medical record

1 in their possession or under their control that pertains to a diagnosed or suspected birth  
2 defect, including the records of the mother.

3 (c) A physician or person in charge of a medical facility who permits examination,  
4 review, or copying of medical records pursuant to this section shall be immune from civil  
5 or criminal liability that might otherwise be incurred or imposed for providing access to  
6 these medical records based upon invasion of privacy or breach of physician-patient  
7 confidentiality.

8 **"§ 130A-131.17. Confidentiality of information; research.**

9 (a) All information collected and analyzed by the Program pursuant to this Part  
10 shall be confidential insofar as the identity of the individual patient is concerned. This  
11 information shall not be considered public record open to inspection. Access to the  
12 information shall be limited to Program staff authorized by the Director of the State  
13 Center for Health and Environmental Statistics. The Director of the State Center for  
14 Health and Environmental Statistics may also authorize access to this information to  
15 persons engaged in demographic, epidemiological, or other similar scientific studies  
16 related to health. The Commission shall adopt rules that establish strict criteria for the  
17 use of monitoring Program information for scientific research. All persons given  
18 authorized access to Program information shall agree, in writing, to maintain  
19 confidentiality.

20 (b) All scientific research proposed to be conducted by persons other than  
21 authorized Program staff using the information from the Program, shall first be reviewed  
22 and approved by the Director of the State Center for Health and Environmental Statistics  
23 and an appropriate committee for the protection of human subjects which is approved by  
24 the United States Department of Health and Human Services pursuant to Part 46 of Title  
25 45 of the Code of Federal Regulations. Satisfaction of the terms of the Commission's  
26 rules for data access shall entitle the researcher to obtain information from the Program  
27 and, if part of the research protocol, to contact case subjects.

28 (c) Whenever authorized Program staff propose a research protocol that includes  
29 contacting case subjects, the Director of the State Center for Health and Environmental  
30 Statistics shall submit a protocol describing the research to the State Health Director and  
31 to an appropriate committee for the protection of human subjects which is approved by  
32 the United States Department of Health and Human Services pursuant to Part 46 of Title  
33 45 of the Code of Federal Regulations. If and when the protocol is approved by the  
34 committee and by the State Health Director pursuant to the rules of the Commission, then  
35 Program staff shall be entitled to complete the approved project and to contact case  
36 subjects.

37 (d) The Program shall maintain a record of all persons who are given access to the  
38 information in the system. The record shall include the following:

- 39 (1) The name of the person authorizing access;
- 40 (2) The name, title, and organizational affiliation of persons given access;
- 41 (3) The dates of access; and
- 42 (4) The specific purposes for which information is to be used.

1 The record required under this subsection shall be open to public inspection during  
2 normal operating hours.

3 (e) Nothing in this section prohibits the Program from publishing statistical  
4 compilations relating to birth defects that do not in any way identify individual patients."

5 Sec. 2. This act becomes effective October 1, 1995.