

GENERAL ASSEMBLY OF NORTH CAROLINA

SESSION 1995

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SENATE BILL 818
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Short Title: Birth Defects/Monitor.

(Public)

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

Referred to: Children and Human Resources

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.

1 (b) Physicians and persons in charge of licensed medical facilities shall, upon
2 request, permit staff of the Program to examine, review, and obtain a copy of any medical
3 record in their possession or under their control that pertains to a diagnosed or suspected
4 birth defect, including the records of the mother.

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

10 **"§ 130A-131.17. Confidentiality of information; research.**

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

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

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

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

- 41 (1) The name of the person authorizing access;
- 42 (2) The name, title, and organizational affiliation of persons given access;
- 43 (3) The dates of access; and

- 1 (4) The specific purposes for which information is to be used.
2 The record required under this subsection shall be open to public inspection during
3 normal operating hours.
4 (e) Nothing in this section prohibits the Program from publishing statistical
5 compilations relating to birth defects that do not in any way identify individual patients."
6 Sec. 2. This act becomes effective October 1, 1995.