
By: **Chairman, Health and Government Operations Committee (By
Request - Departmental - Health and Mental Hygiene)**

Introduced and read first time: February 11, 2005

Assigned to: Health and Government Operations

Committee Report: Favorable with amendments

House action: Adopted

Read second time: March 29, 2005

CHAPTER _____

1 AN ACT concerning

2 **Maryland Birth Defects Program - Authority to Obtain Medical Information**

3 FOR the purpose of clarifying the circumstances under which cases of birth defects
4 must be reported and certain hospital records and other medical information
5 relative to those cases is required to be provided to the Department of Health
6 and Mental Hygiene under Maryland's birth defects reporting law; allowing for
7 the release of the identity of children without birth defects and certain other
8 information to the Department in connection with certain public health
9 investigations; requiring the Department to obtain the informed consent of
10 parents or guardians with or without a birth defect before obtaining certain
11 medical records or including the child in certain research; providing that the
12 release of medical information under certain circumstances is not a breach of
13 patient confidentiality; providing for certain immunity under certain
14 circumstances; requiring the Department to follow certain laws regarding the
15 protection of human subjects; requiring the Department to keep the medical
16 information confidential; and generally relating to birth defects reporting.

17 BY repealing and reenacting, with amendments,
18 Article - Health - General
19 Section 18-206
20 Annotated Code of Maryland
21 (2000 Replacement Volume and 2004 Supplement)

22 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF
23 MARYLAND, That the Laws of Maryland read as follows:

1 **Article - Health - General**

2 18-206.

3 (a) (1) In this section[,] THE FOLLOWING WORDS HAVE THE MEANINGS
4 INDICATED.

5 (2) "[sentinel birth] BIRTH defect" includes:

6 [(1)] (I) Anencephaly;

7 [(2)] (II) Spina bifida;

8 [(3)] (III) Hydrocephaly;

9 [(4)] (IV) Cleft palate;

10 [(5)] (V) Cleft lip;

11 [(6)] (VI) Esophageal atresia and stenosis;

12 [(7)] (VII) Rectal and anal atresia;

13 [(8)] (VIII) Hypospadias;

14 [(9)] (IX) Reduction deformity - upper limb;

15 [(10)] (X) Reduction deformity - lower limb;

16 [(11)] (XI) Congenital dislocation of the hip; and

17 [(12)] (XII) Down syndrome.

18 (3) "HEALTH CARE PROVIDER" HAS THE MEANING STATED IN § 4-301 OF
19 THIS ARTICLE.20 (b) (1) A hospital shall make a report on each child who is [born live]
21 LIVEBORN or stillborn in the hospital and has a [sentinel] birth defect. If a child is
22 born outside the hospital, the person filling out the birth certificate shall make a
23 report under this section.24 (2) The Secretary shall appoint a committee of physicians, hospital
25 representatives, EPIDEMIOLOGISTS, PARENTS OF CHILDREN WITH BIRTH DEFECTS,
26 and officials from the Department to determine the information required under
27 paragraph (1) of this subsection.28 (3) Each month the hospital shall submit the reports for that month to
29 the Department.30 (C) A HEALTH CARE PROVIDER SHALL ALLOW THE DEPARTMENT TO INSPECT
31 AND OBTAIN COPIES OF ANY OF THE FOLLOWING INFORMATION RELATING TO A

1 CHILD WITH A BIRTH DEFECT PROVIDED THAT THE INFORMATION IS USED FOR THE
2 PURPOSES DESCRIBED IN SUBSECTION (F) OF THIS SECTION:

- 3 (1) MEDICAL RECORDS:
4 (I) OF THE CHILD THROUGH THE SECOND YEAR OF LIFE; AND
5 (II) OF THE MOTHER RELATING TO THE PREGNANCY WITH THIS
6 CHILD;
7 (2) RECORDS OF LABORATORY TESTS RELATING TO THE BIRTH DEFECT;
8 AND
9 (3) ANY OTHER MEDICAL INFORMATION RELATING TO THE BIRTH
10 DEFECT.

11 [(c)] (D) (1) The hospital shall disclose the identity of the child with a birth
12 defect, OR A CHILD WITHOUT A BIRTH DEFECT WHO IS PART OF AN INVESTIGATION
13 BY THE DEPARTMENT UNDER PARAGRAPH (2) OF THIS SUBSECTION, to the Secretary
14 so that the Secretary may:

- 15 (i) Use the information to protect the public health; or
16 (ii) Provide the parents OF CHILDREN WITH BIRTH DEFECTS with
17 information on [sentinel] birth defects and public and private services available in
18 accordance with paragraphs (1) and (4) of subsection [(d)] (J) of this section.

19 (2) (I) If the Department shows a need for the individual identity of
20 children without [sentinel] birth defects to conduct [a case-control] AN investigation
21 IN ITS EFFORTS TO PROTECT THE PUBLIC HEALTH, the hospital shall [obtain the
22 written consent of the parent or guardian of the child to disclose the child's name to
23 the Secretary] PROVIDE THE SECRETARY WITH A LIST OF CHILDREN WITH
24 CHARACTERISTICS THAT MEET CRITERIA SPECIFIED BY THE DEPARTMENT FOR ITS
25 INVESTIGATION.

26 ~~(H) THE DEPARTMENT SHALL OBTAIN THE INFORMED CONSENT OF~~
27 ~~THE PARENT OR GUARDIAN OF A CHILD WITHOUT A BIRTH DEFECT BEFORE~~
28 ~~OBTAINING THE MEDICAL RECORDS OF THE CHILD OR INCLUDING THE CHILD IN~~
29 ~~ANY RESEARCH.~~

30 (II) THE DEPARTMENT SHALL OBTAIN THE INFORMED CONSENT OF
31 THE PARENT OR GUARDIAN OF A CHILD WITH OR WITHOUT A BIRTH DEFECT BEFORE:

32 1. OBTAINING THE MEDICAL RECORDS OF THE CHILD FOR
33 ANY RESEARCH REQUIRING APPROVAL BY AN INSTITUTIONAL REVIEW BOARD; OR

34 2. INCLUDING THE CHILD IN ANY RESEARCH REQUIRING
35 APPROVAL BY AN INSTITUTIONAL REVIEW BOARD.

1 (3) The Secretary shall assure that the identity of a child under this
 2 section may not be released OUTSIDE OF THE DEPARTMENT without the written
 3 consent of the parent or guardian of the child.

4 (E) THE DEPARTMENT SHALL KEEP ANY MEDICAL INFORMATION OBTAINED
 5 UNDER THIS SECTION CONFIDENTIAL.

6 (F) MEDICAL INFORMATION REQUESTED UNDER THIS SECTION MUST BE:

7 (1) RELEVANT TO:

8 (I) THE BIRTH DEFECT;

9 ~~(II)~~ (II) ASSURING THE QUALITY OF THE DATA REPORTED;

10 ~~(III)~~ (III) PROVIDING INFORMATION OR SERVICES TO THE CHILD'S
 11 FAMILY;

12 ~~(IV)~~ (IV) CONDUCTING AN EPIDEMIOLOGICAL INVESTIGATION
 13 RELATED TO A BIRTH DEFECT; OR

14 ~~(V)~~ (V) CONDUCTING THE DEPARTMENT'S INSTITUTIONAL
 15 REVIEW BOARD APPROVED RESEARCH INTO THE CAUSES OF BIRTH DEFECTS; AND

16 (2) ONLY AS INTRUSIVE AS NECESSARY.

17 (G) RELEASE OF REPORTS AND OTHER MEDICAL INFORMATION TO THE
 18 DEPARTMENT IN ACCORDANCE WITH THIS SECTION IS NOT A VIOLATION OF THE
 19 CONFIDENTIAL RELATIONSHIP BETWEEN A HEALTH CARE PROVIDER AND A
 20 PATIENT.

21 (H) A HEALTH CARE PROVIDER MAY NOT BE HELD LIABLE FOR DAMAGES AND
 22 IS NOT SUBJECT TO CRIMINAL PENALTIES FOR PROVIDING PATIENT INFORMATION
 23 TO THE DEPARTMENT AS AUTHORIZED BY THIS SECTION.

24 (I) WHENEVER THE DEPARTMENT ENGAGES IN HUMAN SUBJECT RESEARCH,
 25 THE DEPARTMENT IS REQUIRED TO FOLLOW FEDERAL AND STATE LAWS REGARDING
 26 THE PROTECTION OF HUMAN SUBJECTS, INCLUDING OBTAINING APPROPRIATE
 27 INSTITUTIONAL REVIEW BOARD APPROVAL AND FOLLOWING THE BOARD'S
 28 PROTOCOL.

29 [(d)] (J) (1) The Department shall assure that information is prepared and
 30 periodically updated on:

31 (i) [Sentinel birth] BIRTH defects; and

32 (ii) Public and private services for [the disabled] CHILDREN with
 33 [sentinel] birth defects.

34 (2) (i) The Secretary shall appoint a committee to determine the
 35 information required under paragraph (1) of this subsection.

- 1 (ii) The committee shall consist of:
- 2 1. Physicians;
 - 3 2. Educators;
 - 4 3. Social service specialists;
 - 5 4. Representatives of the Department;
 - 6 5. Representatives of the Department of Human Resources;
 - 7 6. Representatives of the Department of Education; and
 - 8 7. Parents of children with [sentinel] birth defects.

9 (3) The information provided under this subsection shall be distributed
10 to each hospital and made available to parents or guardians of children with
11 [sentinel] birth defects by the [infant's] CHILD'S physician before the [infant]
12 CHILD is discharged from the hospital and with an explanation, to the extent possible,
13 of the birth defect to the parents or guardians.

14 (4) (i) The Secretary shall send a letter to the parent or guardian of
15 each child reported under this section with a [sentinel] birth defect before the child is
16 6 months old.

17 (ii) The letter shall offer information about the birth defect and
18 available services with emphasis on needs identified after discharge from the
19 hospital.

20 (iii) Before sending a letter to a parent or guardian, the Secretary
21 shall implement appropriate procedures to assure that a letter is not sent to a parent
22 or guardian of a child who has died.

23 [(e)] (K) The Department and the Department of the Environment shall
24 jointly develop procedures to monitor the data on [sentinel] birth defect trends which
25 may be caused by environmental hazards.

26 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take
27 effect October 1, 2005.