J1 8lr1546

By: Delegate Hubbard

Introduced and read first time: January 29, 2008 Assigned to: Health and Government Operations

A BILL ENTITLED

AN ACT concerning

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Department of Health and Mental Hygiene - Birth Defects Research - Medical Information

FOR the purpose of requiring the Secretary of Health and Mental Hygiene to appoint epidemiologists and parents or guardians of children with birth defects to a certain committee that makes certain reports to the Department of Health and Mental Hygiene concerning certain children born with birth defects; requiring hospitals to submit certain reports to the Department within a certain number of days from a certain date; requiring certain health care providers to allow the Department to inspect and obtain certain medical information regarding certain children with birth defects; requiring a hospital to obtain the consent of certain parents or guardians if the Department shows a need for certain information in the course of an investigation that aids in the protection of the public's health: requiring the Secretary to assure that the identity of certain children is not released outside the Department; requiring the Department to keep certain medical information confidential; requiring certain medical information requested by the Department to be used for certain purposes; providing that the release of certain medical information to the Department is not a violation of a certain confidential relationship; providing that certain health care providers are immune from civil and criminal liability and certain disciplinary action; providing that certain medical information is not subject to certain discovery or use as evidence in certain proceedings; requiring the Department to comply with certain State and federal laws regarding human subject research; defining certain terms; making certain technical changes; and generally relating to the Department of Health and Mental Hygiene and medical information regarding birth defects.

BY repealing and reenacting, with amendments,

Article – Health – General

29 Section 18–206

30 Annotated Code of Maryland

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1	(2005 Replacement Volume and 2007 Supplement)					
2 3	SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:					
4	Article - Health - General					
5	18–206.					
6 7	(a) (1) INDICATED.	In this section[,] THE FOLLOWING WORDS HAVE THE MEANINGS				
8	(2)	["sentinel birth] "BIRTH defect" [includes:				
9	(1)	Anencephaly;				
10	(2)	Spina bifida;				
11	(3)	Hydrocephaly;				
12	(4)	Cleft palate;				
13	(5)	Cleft lip;				
14	(6)	Esophageal atresia and stenosis;				
15	(7)	Rectal and anal atresia;				
16	(8)	Hypospadias;				
17	(9)	Reduction deformity – upper limb;				
18	(10)	Reduction deformity – lower limb;				
19	(11)	Congenital dislocation of the hip; and				
20 21	(12) OR A FUNCTION	Down syndrome] MEANS AN ABNORMALITY OF THE STRUCTURE OF THE HUMAN BODY PRESENT AT BIRTH THAT MAY RESULT IN:				
22		(I) A PHYSICAL OR MENTAL DISABILITY; OR				
23		(II) D EATH.				
24 25	(3) 4–301 OF THIS A	"HEALTH CARE PROVIDER" HAS THE MEANING STATED IN \$				

1 2 3 4	(b) (1) A hospital shall make a report on each child who is [born live] LIVE-BORN or stillborn in the hospital and has a [sentinel] birth defect. If a child is born outside the hospital, the person filling out the birth certificate shall make a report under this section.
5 6 7 8	(2) The Secretary shall appoint a committee of physicians, hospital representatives, EPIDEMIOLOGISTS , PARENTS OR GUARDIANS OF CHILDREN WITH BIRTH DEFECTS , and officials from the Department to determine the information required under paragraph (1) of this subsection.
9 10 11 12	(3) [Each month the] THE hospital shall submit the reports [for that month to the Department] REQUIRED UNDER PARAGRAPH (1) OF THIS SUBSECTION TO THE DEPARTMENT WITHIN 10 DAYS OF THE DATE OF RELEASE OF THE CHILD'S MOTHER FROM THE HOSPITAL .
13 14 15	(C) A HEALTH CARE PROVIDER SHALL ALLOW THE DEPARTMENT TO INSPECT AND OBTAIN THE FOLLOWING MEDICAL INFORMATION REGARDING A CHILD WITH A BIRTH DEFECT:
16	(1) THE MEDICAL RECORDS OF:
17 18	(I) A CHILD THROUGH THE CHILD'S SECOND YEAR OF LIFE;
19 20	(II) A CHILD'S MOTHER REGARDING THE MOTHER'S PREGNANCY WITH THE CHILD;
21 22	(2) RECORDS OF ANY LABORATORY TESTS RELATING TO A CHILD'S BIRTH DEFECT; AND
23 24	(3) ANY OTHER MEDICAL INFORMATION RELATING TO A CHILD'S BIRTH DEFECT.
25 26	[(c)] (D) (1) The hospital shall disclose the identity of the child with a birth defect to the Secretary so that the Secretary may:
27	(i) Use the information to protect the public health; or
28 29 30 31	(ii) Provide the parents OR GUARDIANS OF THE CHILD with information on [sentinel] birth defects and public and private services available in accordance with [paragraphs (1) and (4) of] subsection [(d)] (G)(1) AND (4) of this section.

If the Department shows a need for the individual identity of

children without [sentinel] birth defects to conduct [a case-control] AN investigation

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PENALTIES.

1 THAT AIDS IN THE PROTECTION OF THE PUBLIC HEALTH, the hospital shall obtain 2 the written consent of the parent or guardian of the child to disclose the child's name 3 to the Secretary. 4 The Secretary shall assure that the identity of a child under this section may not be released OUTSIDE THE DEPARTMENT without the written 5 consent of the parent or guardian of the child. 6 7 **(E) (1)** THE DEPARTMENT SHALL KEEP ANY MEDICAL INFORMATION 8 OBTAINED UNDER THIS SECTION CONFIDENTIAL. 9 **(2)** MEDICAL INFORMATION REQUESTED UNDER THIS SECTION 10 SHALL BE ONLY AS INTRUSIVE AS NECESSARY AND USED FOR THE PURPOSE OF: 11 **(I)** ASSURING THE QUALITY OF THE DATA REPORTED; 12 (II)PROVIDING INFORMATION OR SERVICES TO A CHILD'S 13 **FAMILY**; 14 (III) CONDUCTING AN EPIDEMIOLOGICAL INVESTIGATION 15 RELATED TO A BIRTH DEFECT; OR 16 (IV) CONDUCTING THE DEPARTMENT'S RESEARCH INTO THE 17 CAUSES OF BIRTH DEFECTS. 18 **(3)** (I)THE RELEASE OF MEDICAL INFORMATION OBTAINED IN 19 ACCORDANCE WITH THIS SECTION TO THE DEPARTMENT IS NOT A VIOLATION 20OF THE CONFIDENTIAL RELATIONSHIP BETWEEN A HEALTH CARE PROVIDER 21 AND A PATIENT. 22 (II)A HEALTH CARE PROVIDER WHO DISCLOSES MEDICAL 23 RECORDS TO THE DEPARTMENT UNDER THIS SECTION: 241. IS NOT LIABLE IN ANY SUIT FOR CIVIL DAMAGES 25FOR THE DISCLOSURE OF THE MEDICAL RECORDS; 26 2. IS NOT SUBJECT TO DISCIPLINARY ACTION BY ANY 27 LICENSING OR DISCIPLINING AUTHORITY FOR DISCLOSURE OF CONFIDENTIAL 28 **INFORMATION; AND**

MAY NOT BE SUBJECT TO ANY CRIMINAL

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1 2 3 4		INTRO	R THIS SECTION IS NOT SUBJECT TO SUBPOENA, DUCTION INTO EVIDENCE IN ANY ADMINISTRATIVE, CIVIL,					
5 6 7	THIS SECTION,	F) WHILE CONDUCTING RESEARCH USING HUMAN SUBJECTS UNDER ECTION, THE DEPARTMENT SHALL COMPLY WITH THE REQUIREMENTS IE PROTECTION OF HUMAN SUBJECTS UNDER:						
8	(1)	Тіті	LE 13, SUBTITLE 20 OF THIS ARTICLE; AND					
9	(2)	42 T	J.S.C. § 289.					
10 11	[(d)] (G) and periodically u		The Department shall assure that information is prepared on:					
12		(i)	[Sentinel birth] BIRTH defects; and					
13 14	CHILDREN WITH	(ii) birth	Public and private services for [the disabled with sentinel] defects.					
15 16	(2) information requi	(i) red un	The Secretary shall appoint a committee to determine the der paragraph (1) of this subsection.					
17		(ii)	The committee shall consist of:					
18			1. Physicians;					
19			2. Educators;					
20			3. Social service specialists;					
21			4. Representatives of the Department;					
22 23	Resources;		5. Representatives of the Department of Human					
24			6. Representatives of the Department of Education; and					
25			7. Parents of children with [sentinel] birth defects.					
26 27 28 29	with [sentinel] b	ch hos irth de	information provided under this subsection shall be pital and made available to parents or guardians of children efects by the [infant's] CHILD'S physician before the [infant] m the hospital and with an explanation, to the extent possible,					

of the birth defect to the parents or guardians.

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1	(4) (i) The Secretary shall send a letter to the parent or guardian					
2	of each child reported under this section with a [sentinel] birth defect before the child					
3	is 6 months old.					
4	(ii) The letter shall offer information about the birth defect and					
5	available services with emphasis on needs identified after discharge from the hospital.					
6	(iii) Before sending a letter to a parent or guardian, the					
7	Secretary shall implement appropriate procedures to assure that a letter is not sent to					
8	a parent or guardian of a child who has died.					
9	[(e)] (H) The Department and the Department of the Environment shall					
10	jointly develop procedures to monitor the data on [sentinel] birth defect trends which					
11	may be caused by environmental hazards.					
12	SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect					
13	October 1, 2008.					