J1 8lr2948 CF HB 438

By: Senator Conway

Introduced and read first time: February 8, 2008

Assigned to: Rules

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.

27 BY repealing and reenacting, with amendments,

Article – Health – General

29 Section 18–206

30 Annotated Code of Maryland

1	(2005 Replacement Volume and 2007 Supplement)					
2 3			BE IT ENACTED BY THE GENERAL ASSEMBLY OF the Laws of Maryland read as follows:			
4			Article - Health - General			
5	18–206.					
6 7	(a) (1 INDICATED.	1) In	this section[,] THE FOLLOWING WORDS HAVE THE MEANINGS			
8	(2	2) ["	sentinel birth] "BIRTH defect" [includes:			
9	(1	l) Ar	nencephaly;			
10	(2	2) Sp	oina bifida;			
11	(3	3) Hy	ydrocephaly;			
12	(4	4) Cl	eft palate;			
13	(5	5) Cl	eft lip;			
14	(6	B) Es	sophageal atresia and stenosis;			
15	(7	7) Re	ectal and anal atresia;			
16	8)	3) Hy	ypospadias;			
17	(9	e) Re	eduction deformity – upper limb;			
18	(1	lo) Re	eduction deformity – lower limb;			
19	(1	(11) Co	ongenital dislocation of the hip; and			
20 21	•		own syndrome] MEANS AN ABNORMALITY OF THE STRUCTURE THE HUMAN BODY PRESENT AT BIRTH THAT MAY RESULT IN:			
22		(I)	A PHYSICAL OR MENTAL DISABILITY; OR			
23		(11	I) DEATH .			
24 25	(§ 4–301 of thi		HEALTH CARE PROVIDER" HAS THE MEANING STATED IN §			

1	(b) (1) A hospital shall make a report on each child who is [born live]					
2	LIVE-BORN or stillborn in the hospital and has a [sentinel] birth defect. If a child is					
3	born outside the hospital, the person filling out the birth certificate shall make a					
4	report under this section.					
5	(2) The Secretary shall appoint a committee of physicians, hospital					
6	representatives, EPIDEMIOLOGISTS, PARENTS OR GUARDIANS OF CHILDREN					
7	WITH BIRTH DEFECTS, and officials from the Department to determine the					
8	information required under paragraph (1) of this subsection.					
O	information required under paragraph (1) of this subsection.					
9	(3) [Each month the] THE hospital shall submit the reports [for that					
10	month to the Department] REQUIRED UNDER PARAGRAPH (1) OF THIS					
11	SUBSECTION TO THE DEPARTMENT WITHIN 10 DAYS OF THE DATE OF RELEASE					
12	OF THE CHILD'S MOTHER FROM THE HOSPITAL.					
13	(C) A HEALTH CARE PROVIDER SHALL ALLOW THE DEPARTMENT TO					
14	INSPECT AND OBTAIN THE FOLLOWING MEDICAL INFORMATION REGARDING A					
15	CHILD WITH A BIRTH DEFECT:					
16	(1) THE MEDICAL RECORDS OF:					
17	(I) A CHILD THROUGH THE CHILD'S SECOND YEAR OF LIFE					
18	AND					
10						
19	(II) A CHILD'S MOTHER REGARDING THE MOTHER'S					
20	PREGNANCY WITH THE CHILD;					
20	THEORIMOT WITH THE CHIED,					
21	(2) RECORDS OF ANY LABORATORY TESTS RELATING TO A					
22	CHILD'S BIRTH DEFECT; AND					
	CHILD'S BIRTH DEFECT, AND					
23	(3) Any other medical information relating to a child's					
$\frac{26}{24}$	BIRTH DEFECT.					
4 1	BILLIII DEFECT.					
25	[(c)] (D) (1) The hospital shall disclose the identity of the child with a birth					
26	defect to the Secretary so that the Secretary may:					
20	defect to the Secretary so that the Secretary may.					
27	(i) Use the information to protect the public health; or					
_,	(2) 0 0 0 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1					
28	(ii) Provide the parents OR GUARDIANS OF THE CHILD with					
29	information on [sentinel] birth defects and public and private services available in					
30	accordance with [paragraphs (1) and (4) of] subsection [(d)] (G)(1) AND (4) of this					
31	section.					
32	(2) 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 to the Secretary. 3 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	(4) DEPARTMENT DISCOVERY, OR I	NTRO:	R THIS SECTION IS NOT SUBJECT TO SUBPOENA, DUCTION INTO EVIDENCE IN ANY ADMINISTRATIVE, CIVIL,				
5 6 7	(F) WHILE CONDUCTING RESEARCH USING HUMAN SUBJECTS UNDER THIS SECTION, THE DEPARTMENT SHALL COMPLY WITH THE REQUIREMENTS FOR THE PROTECTION OF HUMAN SUBJECTS UNDER:						
8	(1)	TITL	E 13, SUBTITLE 20 OF THIS ARTICLE; AND				
9	(2)	42 L	J.S.C. § 289.				
10 11	[(d)] (G) and periodically u	(1) pdated	The Department shall assure that information is prepared on:				
12		(i)	[Sentinel birth] BIRTH defects; and				
13 14	CHILDREN WITH	(ii) birth o	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] bi	h hosp rth de	information provided under this subsection shall be pital and made available to parents or guardians of children fects 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) (1) 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.					
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