By: Senator Conway

Introduced and read first time: February 8, 2008

Assigned to: Rules

Re-referred to: Education, Health, and Environmental Affairs, February 14, 2008

Committee Report: Favorable with amendments

Senate action: Adopted

Read second time: March 19, 2008

CHAPTER

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 period of time after 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

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

<u>Underlining</u> indicates amendments to bill.

Strike out indicates matter stricken from the bill by amendment or deleted from the law by amendment.

$\frac{1}{2}$	technical changes; and generally relating to the Department of Health and Mental Hygiene and medical information regarding birth defects.						
3 4 5 6 7	BY repealing and reenacting, with amendments, Article – Health – General Section 18–206 Annotated Code of Maryland (2005 Replacement Volume and 2007 Supplement)						
8 9	SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:						
10	Article - Health - General						
1	18–206.						
12 13	(a) INDICATED	(1)	In this section[,] THE FOLLOWING WORDS HAVE THE MEANINGS				
L 4		(2)	["sentinel birth] "BIRTH defect" [includes:				
15		(1)	Anencephaly;				
16		(2)	Spina bifida;				
L 7		(3)	Hydrocephaly;				
18		(4)	Cleft palate;				
19		(5)	Cleft lip;				
20		(6)	Esophageal atresia and stenosis;				
21		(7)	Rectal and anal atresia;				
22		(8)	Hypospadias;				
23		(9)	Reduction deformity – upper limb;				
24		(10)	Reduction deformity – lower limb;				
25		(11)	Congenital dislocation of the hip; and				
26 27	OR A FUNCT	(12) FION (Down syndrome] MEANS AN ABNORMALITY OF THE STRUCTURE OF THE HUMAN BODY PRESENT AT BIRTH THAT MAY RESULT IN:				

1	(II) D EATH.					
2 3	(3) "Health care provider" has the meaning stated in \S 4–301 of this article.					
4 5 6 7	(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.					
8 9 10 11	(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.					
12 13 14 15	(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 1 MONTH AFTER THE DATE OF RELEASE OF THE CHILD'S MOTHER FROM THE HOSPITAL.					
16 17 18	(C) A HEALTH CARE PROVIDER SHALL ALLOW THE DEPARTMENT TO INSPECT AND OBTAIN THE FOLLOWING MEDICAL INFORMATION REGARDING A CHILD WITH A BIRTH DEFECT:					
19	(1) THE MEDICAL RECORDS OF:					
20 21	(I) A CHILD THROUGH THE CHILD'S SECOND YEAR OF LIFE;					
22 23	(II) A CHILD'S MOTHER REGARDING THE MOTHER'S PREGNANCY WITH THE CHILD;					
24 25	(2) RECORDS OF ANY LABORATORY TESTS RELATING TO A CHILD'S BIRTH DEFECT; AND					
26 27	(3) ANY OTHER MEDICAL INFORMATION RELATING TO A CHILD'S BIRTH DEFECT.					
28 29	[(c)] (D) (1) The hospital shall disclose the identity of the child with a birth defect to the Secretary so that the Secretary may:					
30	(i) Use the information to protect the public health; or					

1 2 3 4	(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.						
5 6 7 8 9	(2) If the Department shows a need for the individual identity of children without [sentinel] birth defects to conduct [a case—control] AN investigation THAT AIDS IN THE PROTECTION OF THE PUBLIC HEALTH , the hospital shall obtain the written consent of the parent or guardian of the child to disclose the child's name to the Secretary.						
10 11 12	(3) The Secretary shall assure that the identity of a child under this section may not be released OUTSIDE THE DEPARTMENT without the written consent of the parent or guardian of the child.						
13 14	(E) (1) THE DEPARTMENT SHALL KEEP ANY MEDICAL INFORMATION OBTAINED UNDER THIS SECTION CONFIDENTIAL.						
15 16	(2) MEDICAL INFORMATION REQUESTED UNDER THIS SECTION SHALL BE ONLY AS INTRUSIVE AS NECESSARY AND USED FOR THE PURPOSE OF:						
17	(I) ASSURING THE QUALITY OF THE DATA REPORTED;						
18 19	(II) PROVIDING INFORMATION OR SERVICES TO A CHILD'S FAMILY;						
20 21	(III) CONDUCTING AN EPIDEMIOLOGICAL INVESTIGATION RELATED TO A BIRTH DEFECT; OR						
22 23	(IV) CONDUCTING THE DEPARTMENT'S RESEARCH INTO THE CAUSES OF BIRTH DEFECTS.						
24252627	(3) (I) THE RELEASE OF MEDICAL INFORMATION OBTAINED IN ACCORDANCE WITH THIS SECTION TO THE DEPARTMENT IS NOT A VIOLATION OF THE CONFIDENTIAL RELATIONSHIP BETWEEN A HEALTH CARE PROVIDER AND A PATIENT.						
28 29	(II) A HEALTH CARE PROVIDER WHO DISCLOSES MEDICAL RECORDS TO THE DEPARTMENT UNDER THIS SECTION:						
30 31	1. IS NOT LIABLE IN ANY SUIT FOR CIVIL DAMAGES FOR THE DISCLOSURE OF THE MEDICAL RECORDS;						

1		2.	IS NOT SUBJECT TO DISCIPLINARY ACTION BY ANY				
$\frac{2}{3}$	LICENSING OR I		NG AUTHORITY FOR DISCLOSURE OF CONFIDENTIAL				
4		3.	MAY NOT BE SUBJECT TO ANY CRIMINAL				
5	PENALTIES.						
6	(4)	ТНЕ МІ	EDICAL INFORMATION OBTAINED BY THE				
7			HIS SECTION IS NOT SUBJECT TO SUBPOENA,				
8 9	DISCOVERY, OR INTRODUCTION INTO EVIDENCE IN ANY ADMINISTRATIVE, CIVIL, OR CRIMINAL PROCEEDING.						
Ü	OR CRIMINAL I I	ioceeding.	•				
10			CTING RESEARCH USING HUMAN SUBJECTS UNDER				
$\frac{11}{12}$	·		RTMENT SHALL COMPLY WITH THE REQUIREMENTS IUMAN SUBJECTS UNDER:				
		orion or in	iemmi Sebele is endem.				
13	(1)	TITLE 13,	, SUBTITLE 20 OF THIS ARTICLE; AND				
14	(2)	42 U.S.C.	. § 289.				
15 16	[(d)] (G) and periodically u		e Department shall assure that information is prepared				
17		(i) [Sen	ntinel birth] BIRTH defects; and				
18 19	CHILDREN WITH		olic and private services for [the disabled with sentinel] ts.				
20 21	(2) information requi		e Secretary shall appoint a committee to determine the aragraph (1) of this subsection.				
22		(ii) The	e committee shall consist of:				
23		1.	Physicians;				
24		2.	Educators;				
25		3.	Social service specialists;				
26		4.	Representatives of the Department;				
27 28	Resources;	5.	Representatives of the Department of Human				
29		6.	Representatives of the Department of Education; and				

1	7. Parents of children with [sentinel] birth defects.						
2 3 4 5 6	distributed to each hospital and made available to parents or guardians of children with [sentinel] birth defects by the [infant's] CHILD'S physician before the [infant CHILD is discharged from the hospital and with an explanation, to the extent possible						
7 8 9	(4) (i) The Secretary shall send a letter to the parent or guardian of each child reported under this section with a [sentinel] birth defect before the child is 6 months old.						
10 11	(ii) The letter shall offer information about the birth defect and available services with emphasis on needs identified after discharge from the hospital.						
12 13 14	(iii) Before sending a letter to a parent or guardian, the Secretary shall implement appropriate procedures to assure that a letter is not sent to a parent or guardian of a child who has died.						
15 16 17	[(e)] (H) The Department and the Department of the Environment shall jointly develop procedures to monitor the data on [sentinel] birth defect trends which may be caused by environmental hazards.						
18 19	SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2008.						
	Approved:						
	Governor.						
	President of the Senate.						
	Speaker of the House of Delegates.						