HOUSE BILL 1161

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By: Delegates Szeliga, Arikan, Chisholm, Grammer, M. Morgan, Nawrocki, and Reilly

Introduced and read first time: February 10, 2023 Assigned to: Health and Government Operations

A BILL ENTITLED

AN ACT concerning 1

$\mathbf{2}$ Public Health - Human Papillomavirus Vaccine - Information and Informed Consent 3 (Christina's Law) 4

5	FOR the purpose of requiring a health care provider, before each administration of a human
6	papillomavirus (HPV) vaccine, to provide an individual or an individual's parent or
$\overline{7}$	guardian with a certain information sheet and obtain written consent on a certain
8	form; and generally relating to information on, and informed consent regarding, the
9	human papillomavirus vaccine.

- 10 BY adding to
- Article Health General 11
- Section 18-342 through 18-344 to be under the new part "Part VII. Human 12Papillomavirus" 13
- Annotated Code of Maryland 14
- (2019 Replacement Volume and 2022 Supplement) 15
- SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, 16 17That the Laws of Maryland read as follows:

18		Article – Health – General
19	18-340. RESERVED.	
20	18–341. RESERVED.	
21		PART VII. HUMAN PAPILLOMAVIRUS.

PART VII. HUMAN PAPILLOMAVIRUS.

2218 - 342.

> EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW. [Brackets] indicate matter deleted from existing law.



1 (A) IN THIS PART THE FOLLOWING WORDS HAVE THE MEANINGS 2 INDICATED.

3 (B) "ADVERSE EVENT" MEANS ANY ILLNESS, DISABILITY, INCAPACITY, 4 HOSPITALIZATION, DEATH, OR IMPAIRMENT OF MENTAL, EMOTIONAL, BEHAVIORAL, 5 OR PHYSICAL FUNCTIONING OR DEVELOPMENT, THE FIRST MANIFESTATION OF 6 WHICH APPEARS AFTER THE DATE OF ADMINISTRATION OF AN HPV VACCINE.

7 (C) "HEALTH CARE PROVIDER" MEANS A LICENSED HEALTH CARE
8 PROFESSIONAL, ORGANIZATION, OR INSTITUTION, WHETHER PUBLIC OR PRIVATE,
9 UNDER WHOSE AUTHORITY AN HPV VACCINE IS ADMINISTERED.

10 (D) "HPV" MEANS THE HUMAN PAPILLOMAVIRUS.

11 (E) "HPV VACCINE" MEANS ANY VACCINE THAT CONTAINS MATERIALS 12 INTENDED TO PREVENT THE OCCURRENCE OF HPV, WHETHER THE MATERIALS ARE 13 ADMINISTERED SEPARATELY OR IN CONJUNCTION WITH OTHER MATERIALS 14 INTENDED TO PREVENT THE OCCURRENCE OF OTHER DISEASES.

15 (F) "MARYLAND SUPPLEMENTAL INFORMATION SHEET" MEANS A 16 DOCUMENT THAT PROVIDES A POTENTIAL HPV VACCINE RECIPIENT OR THE 17 PARENT OR GUARDIAN OF A POTENTIAL HPV VACCINE RECIPIENT WITH 18 ADDITIONAL INFORMATION THAT IS NECESSARY FOR MAKING AN INFORMED 19 DECISION WHETHER OR NOT TO CONSENT TO INOCULATIONS WITH AN HPV 20 VACCINE.

21 **18–343.**

22 (A) (1) BEFORE EACH ADMINISTRATION OF AN HPV VACCINE, A HEALTH 23 CARE PROVIDER SHALL:

24 (I) PROVIDE TO THE INDIVIDUAL OR THE INDIVIDUAL'S 25 PARENT OR GUARDIAN A MARYLAND SUPPLEMENTAL INFORMATION SHEET; AND

26 (II) OBTAIN A SIGNED MARYLAND HPV VACCINE CONSENT 27 FORM.

28 (2) THE MARYLAND SUPPLEMENTAL INFORMATION SHEET 29 PROVIDED UNDER PARAGRAPH (1) OF THIS SUBSECTION SHALL INCLUDE, AT A 30 MINIMUM, THE FOLLOWING STATEMENTS RELATING TO HPV AND HPV VACCINES:

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(I) HPV IS A VERY COMMON VIRAL INFECTION THAT IS

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1	TRANSMITTED PRIMARILY THROUGH SEXUAL CONTACT;		
2	(II)	RISH	AS ASSOCIATED WITH HPV VACCINES INCLUDE:
3		1.	DEATH;
4		2.	SWOLLEN GLANDS;
5		3.	PULMONARY EMBOLISM;
6		4.	NAUSEA;
7		5.	PANCREATITIS;
8		6.	VOMITING;
9		7.	EXTREME FATIGUE;
10		8.	DIZZINESS;
11		9.	AUTOIMMUNE DISORDERS;
12		10.	BRONCHOSPASM;
13		11.	HIVES;
14		12.	RASH;
15		13.	ANAPHYLACTIC REACTION;
16		14.	JOINT AND MUSCLE PAIN AND WEAKNESS;
17		15.	ENCEPHALOMYELITIS;
18		16.	HEADACHE;
19		17.	GUILLAIN-BARRE SYNDROME;
20		18.	DIFFICULTY BREATHING;
21		19.	HEART ARRHYTHMIA;
22		20.	MOTOR NEURON DISEASE;

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1	21. PARALYSIS;
2	22. PREMATURE OVARIAN FAILURE;
3	23. SEIZURES;
4	24. Syncope;
5	25. TRANSVERSE MYELITIS;
6	26. CELLULITIS; AND
7	27. IDIOPATHIC THROMBOCYTOPENIA; AND
8 9	(III) ADVERSE EVENTS FOLLOWING HPV VACCINATION CAN OCCUR MINUTES, HOURS, DAYS, WEEKS, OR MONTHS AFTER HPV VACCINATION.
10 11 12 13	(3) THE MARYLAND SUPPLEMENTAL INFORMATION SHEET REQUIRED TO BE PROVIDED UNDER PARAGRAPH (1) OF THIS SUBSECTION SHALL INCLUDE INFORMATION ON THE INDIVIDUAL'S RIGHTS IF THE INDIVIDUAL IS HARMED BY AN HPV VACCINE, INCLUDING:
14 15 16	(I) THAT AN INDIVIDUAL WHO IS INJURED BY AN HPV VACCINE CANNOT SUE THE PHARMACEUTICAL COMPANY OR THE PROVIDER OF THE HPV VACCINE;
17 18	(II) CONTACT INFORMATION FOR THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM;
19 20	(III) THAT THERE IS NO GUARANTEE OF COMPENSATION EVEN IF AN INDIVIDUAL SUFFERS HARM FROM AN HPV VACCINE;
$\begin{array}{c} 21 \\ 22 \end{array}$	(IV) THE TIME LIMIT FOR FILING A SUIT AGAINST A HEALTH CARE PROVIDER, AS PROVIDED IN § 5–109 OF THE COURTS ARTICLE; AND
$\frac{23}{24}$	(V) THAT THE INDIVIDUAL MAY FILE A COMPLAINT WITH THE DEPARTMENT.
$25 \\ 26 \\ 27$	(B) (1) A HEALTH CARE PROVIDER SHALL OBTAIN THE WRITTEN CONSENT OF AN INDIVIDUAL OR THE INDIVIDUAL'S PARENT OR GUARDIAN ON A MARYLAND HPV VACCINE CONSENT FORM DEVELOPED BY THE DEPARTMENT:

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BEFORE THE ADMINISTRATION OF A MARYLAND HPV 1 **(I)** $\mathbf{2}$ VACCINE; AND 3 **(II)** AFTER FULFILLING THE REQUIREMENTS OF SUBSECTION (A) OF THIS SECTION. 4 (2) THE MARYLAND HPV VACCINE CONSENT FORM SHALL INCLUDE: $\mathbf{5}$ 6 **(I)** A STATEMENT THAT THE INDIVIDUAL OR THE INDIVIDUAL'S 7 PARENT OR GUARDIAN HAS BEEN INFORMED BY THE PROVIDER THAT THE INDIVIDUAL OR THE INDIVIDUAL'S PARENT OR GUARDIAN HAS A RIGHT TO DECLINE 8 9 ANY HPV VACCINE; 10 **(II)** A STATEMENT THAT THE INDIVIDUAL HAS RECEIVED A 11 COPY OF THE MARYLAND SUPPLEMENTAL INFORMATION SHEET AND HAS HAD THE 12**OPPORTUNITY TO READ IT AND ASK QUESTIONS;** 13 (III) A STATEMENT THAT THE INDIVIDUAL HAS BEEN INFORMED 14 THAT THERE HAVE BEEN NO LONG-TERM HEALTH-OUTCOME STUDIES REGARDING 15THE SAFETY OF CONCOMITANT VACCINATION: 16 (IV) A STATEMENT THAT THE INDIVIDUAL UNDERSTANDS THAT IF THE INDIVIDUAL OR THE INDIVIDUAL'S CHILD IS HARMED BY THE VACCINE, THE 17INDIVIDUAL CANNOT SUE THE PROVIDER OR THE MANUFACTURER; 18 19 **(**V**)** A STATEMENT THAT THE INDIVIDUAL UNDERSTANDS THAT 20THERE IS NO GUARANTEE THAT BY RECEIVING THE VACCINE THE INDIVIDUAL OR THE INDIVIDUAL'S CHILD WILL BE PROTECTED FROM THE DISEASE THE VACCINE IS 2122**ALLEGED TO PREVENT; AND** 23(VI) DATED SIGNATURES OF THE INDIVIDUAL, OR THE 24INDIVIDUAL'S PARENT OR GUARDIAN, AND THE PROVIDER. 25A HEALTH CARE PROVIDER ACTING IN GOOD FAITH MAY NOT BE HELD **(C)** LIABLE IN ANY CAUSE OF ACTION FOR PROVIDING AN INDIVIDUAL OR AN 26INDIVIDUAL'S PARENT OR GUARDIAN WITH THE MARYLAND SUPPLEMENTAL 2728INFORMATION SHEET UNDER SUBSECTION (A) OF THIS SECTION. 2918-344. 30 THE DEPARTMENT SHALL ADOPT REGULATIONS ESTABLISHING: 31 (1) THE CONTENT OF THE MARYLAND SUPPLEMENTAL INFORMATION

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1	SHEET;		
2	(2) THE CONTENT OF THE MARYLAND HPV VACCINE CONSENT		
3	FORM;		
4	(3) PROCEDURES TO DISTRIBUTE COPIES OF THE MARYLAND		
$\frac{4}{5}$			
-	SUPPLEMENTAL INFORMATION SHEET AND MARYLAND HPV VACCINE CONSENT		
6	FORM IN MULTIPLE LANGUAGES;		
7	(4) PROCEDURES TO NOTIFY PROVIDERS OF THE CONTENT OF THE		
8	MARYLAND SUPPLEMENTAL INFORMATION SHEET AND MARYLAND HPV VACCINE		
9	CONSENT FORM; AND		
10	(5) PROCEDURES PERIODICALLY TO REVISE AND UPDATE THE		
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11	INFORMATION REQUIRED UNDER § $18-343$ OF THIS SUBTITLE.		

12 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect 13 October 1, 2023.