

HOUSE BILL 1332

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9lr3067
CF SB 783

By: **Delegate Szeliga**

Introduced and read first time: February 15, 2019

Assigned to: Rules and Executive Nominations

A BILL ENTITLED

1 AN ACT concerning

2 **Public Health – Human Papillomavirus Vaccine – Information and Informed**
3 **Consent**
4 **(Christina’s Law)**

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
7 guardian with a certain information sheet and obtain written consent on a certain
8 form; requiring that a certain information sheet include, at a minimum, certain
9 statements; requiring that a certain consent form developed by the Maryland
10 Department of Health include certain information; providing that a health care
11 provider may not be held liable for providing certain information to certain
12 individuals or for reporting certain information to a certain reporting system;
13 requiring a health care provider to record in a certain permanent record certain
14 information at the time of administration of an HPV vaccine; requiring the
15 Department to adopt certain regulations; defining certain terms; and generally
16 relating to information on, and informed consent regarding, the human
17 papillomavirus vaccine.

18 BY adding to

19 Article – Health – General
20 Section 18–341 through 18–344 to be under the new part “Part VII. Human
21 Papillomavirus”
22 Annotated Code of Maryland
23 (2015 Replacement Volume and 2018 Supplement)

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

26 **Article – Health – General**

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 **18-340. RESERVED.**

2 **PART VII. HUMAN PAPILLOMAVIRUS.**

3 **18-341.**

4 (A) IN THIS PART THE FOLLOWING WORDS HAVE THE MEANINGS
5 INDICATED.

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

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

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

14 (E) "HPV VACCINE" MEANS ANY VACCINE THAT CONTAINS MATERIALS
15 INTENDED TO PREVENT THE OCCURRENCE OF HPV, WHETHER OR NOT THE
16 MATERIALS ARE ADMINISTERED SEPARATELY OR IN CONJUNCTION WITH OTHER
17 MATERIALS INTENDED TO PREVENT THE OCCURRENCE OF OTHER DISEASES.

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

24 (G) "VAERS" MEANS THE NATIONAL VACCINE ADVERSE EVENT
25 SURVEILLANCE PROGRAM ADMINISTERED BY THE CENTERS FOR DISEASE
26 CONTROL AND PREVENTION AND THE FOOD AND DRUG ADMINISTRATION.

27 **18-342.**

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

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

1 **(II) OBTAIN A SIGNED MARYLAND HPV VACCINE CONSENT**
2 **FORM.**

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

6 **(I) HPV IS A VERY COMMON VIRAL INFECTION WHICH IS**
7 **TRANSMITTED PRIMARILY THROUGH SEXUAL CONTACT;**

8 **(II) 1. THERE ARE MORE THAN 150 STRAINS OF HPV AND**
9 **WHILE MILLIONS OF AMERICANS ARE INFECTED WITH HPV, THE VIRUSES ARE**
10 **CLEARED WITHOUT ANY TREATMENT IN THE VAST MAJORITY OF CASES; AND**

11 **2. AN INDIVIDUAL'S IMMUNE SYSTEM CLEARS**
12 **APPROXIMATELY 90% TO 95% OF HPV INFECTIONS WITHIN 2 YEARS;**

13 **(III) 1. APPROXIMATELY 15 STRAINS OF HPV ARE**
14 **ASSOCIATED WITH CERVICAL CANCER AND ARE CLASSIFIED AS HIGH RISK;**

15 **2. IF AN INFECTION FROM A HIGH RISK STRAIN OF HPV**
16 **PERSISTS FOR DECADES WITHOUT TREATMENT, THE INFECTION COULD LEAD TO**
17 **CERVICAL CANCER;**

18 **3. CERTAIN HPV VACCINES MAY STIMULATE THE BODY**
19 **TO PRODUCE ANTIBODIES AGAINST SOME, BUT NOT ALL, HIGH RISK HPV STRAINS;**
20 **AND**

21 **4. IT IS ASSUMED, BUT NOT PROVEN, THAT THE**
22 **INCREASED ANTIBODIES FROM AN HPV VACCINE WILL PREVENT CANCERS**
23 **ASSOCIATED WITH HIGH RISK HPV STRAINS;**

24 **(IV) CERTAIN STRAINS OF HPV MAY CONTRIBUTE TO AN**
25 **INCREASED RISK OF CERVICAL CANCER; HOWEVER, OTHER RISK FACTORS NEED TO**
26 **BE PRESENT, INCLUDING:**

27 **1. SMOKING;**

28 **2. ALCOHOL CONSUMPTION;**

29 **3. FAMILY MEDICAL HISTORY OF CANCER;**

1 4. **HUMAN IMMUNODEFICIENCY VIRUS (HIV)**
2 **INFECTION;**

3 5. **A WEAKENED IMMUNE SYSTEM;**

4 6. **THE PRESENCE OF OTHER SEXUALLY TRANSMITTED**
5 **INFECTIONS; AND**

6 7. **HORMONAL FACTORS;**

7 (v) 1. **THE STATISTICAL LIKELIHOOD OF DEVELOPING**
8 **CERVICAL CANCER IS LESS THAN 1% FOR INDIVIDUALS AT AN AVERAGE AGE OF 49**
9 **YEARS OLD; AND**

10 2. **THE DEATH RATE FOR CERVICAL CANCER IN THE**
11 **UNITED STATES IS 1.7 PER 100,000 INDIVIDUALS;**

12 (vi) 1. **MOST CERVICAL CANCER IS PREVENTABLE AND**
13 **TREATABLE WITH PAP SCREENING;**

14 2. **EVEN IF AN INDIVIDUAL RECEIVES AN HPV VACCINE,**
15 **THE INDIVIDUAL SHOULD RECEIVE REGULAR PAP SCREENING BECAUSE THE HPV**
16 **VACCINE DOES NOT PREVENT ALL HIGH RISK STRAINS OF HPV WHICH MAY CAUSE**
17 **CERVICAL CANCER;**

18 3. **PAP SCREENING HAS REDUCED THE INCIDENCE OF**
19 **CERVICAL CANCER BY 75% SINCE SCREENING WAS INTRODUCED; AND**

20 4. **BECAUSE HPV VACCINES DO NOT ADDRESS ALL HIGH**
21 **RISK HPV STRAINS, PAP SCREENING CONTINUES TO BE NECESSARY;**

22 (vii) **THE EFFECTIVENESS OF AN HPV VACCINE IS UNKNOWN,**
23 **AND SOME INDIVIDUALS SHOW NO MEASURABLE HPV ANTIBODIES 5 YEARS AFTER**
24 **RECEIVING THE VACCINE;**

25 (viii) **AN HPV VACCINE MUST BE ADMINISTERED BEFORE AN**
26 **INDIVIDUAL IS EXPOSED TO HPV BECAUSE:**

27 1. **AN HPV VACCINE IS NOT EFFECTIVE AGAINST HPV**
28 **STRAINS ALREADY PRESENT IN AN INDIVIDUAL; AND**

29 2. **IF AN INDIVIDUAL IS INFECTED WITH CERTAIN**
30 **STRAINS OF HPV AT THE TIME OF INOCULATION, THE INDIVIDUAL'S RISK OF**

1 DEVELOPING CERVICAL CANCER MAY INCREASE BY APPROXIMATELY 44.6%;

2 (IX) CONDOMS REDUCE THE RISK OF HPV INFECTION, BUT DO
3 NOT PROVIDE COMPLETE PROTECTION;

4 (X) 1. HPV VACCINES CAN PREVENT LOW RISK STRAINS OF
5 VIRUSES THAT MAY CAUSE GENITAL WARTS; AND

6 2. THE DURATION OF THE EFFECTIVENESS OF THE
7 ANTIBODIES FROM HPV VACCINATION IS UNKNOWN;

8 (XI) 1. GARDASIL 9 IS THE ONLY HPV VACCINE AVAILABLE
9 IN THE UNITED STATES;

10 2. GARDASIL 9 CONTAINS YEAST, ALUMINUM, AND
11 OTHER NEUROTOXINS LIKE POLYLOBATE 80 AND SODIUM BORATE;

12 3. THERE IS POTENTIAL FOR SERIOUS ALUMINUM
13 TOXICITY IN VULNERABLE POPULATIONS;

14 4. ANYONE WITH AN ALLERGY TO ANY COMPONENT OF
15 HPV VACCINES, INCLUDING AN ALLERGY TO YEAST SHOULD NOT GET THE VACCINE;

16 5. HPV VACCINES HAVE NOT BEEN EVALUATED FOR
17 CARCINOGENICITY OR IMPACT ON REPRODUCTION, AND THEY ARE NOT
18 RECOMMENDED FOR USE IN PREGNANT WOMEN; AND

19 6. ADVERSE EVENTS FOLLOWING HPV VACCINATION
20 SHOULD BE REPORTED BY BOTH THE CONSUMER AND THE PROVIDER TO THE
21 VAERS;

22 (XII) HPV VACCINES ARE RECOMMENDED FOR MALES BECAUSE
23 MALES CAN TRANSMIT HPV TO THEIR SEXUAL PARTNERS AND HPV VACCINES MAY
24 PREVENT CERTAIN STRAINS OF HPV THAT MAY CAUSE GENITAL WARTS;

25 (XIII) 1. CERTAIN HIGH RISK STRAINS OF HPV MAY INCREASE
26 RISK FOR VAGINAL, VULVA, PENILE, THROAT, AND ANAL CANCERS, BUT OTHER RISK
27 FACTORS FOR THESE CANCERS ALSO INCLUDE SMOKING, ALCOHOL CONSUMPTION,
28 HIV INFECTION, AND A COMPROMISED IMMUNE SYSTEM; AND

29 2. HPV VACCINES HAVE NOT BEEN PROVEN TO
30 PREVENT VAGINAL, VULVA, PENILE, THROAT, AND ANAL CANCERS;

(XIV) RISKS ASSOCIATED WITH HPV VACCINES INCLUDE:

1. **DEATH;**
2. **SWOLLEN GLANDS;**
3. **PULMONARY EMBOLISM;**
4. **NAUSEA;**
5. **PANCREATITIS;**
6. **VOMITING;**
7. **EXTREME FATIGUE;**
8. **DIZZINESS;**
9. **AUTOIMMUNE DISORDERS;**
10. **BRONCHOSPASM;**
11. **HIVES;**
12. **RASH;**
13. **ANAPHYLACTIC REACTION;**
14. **JOINT AND MUSCLE PAIN AND WEAKNESS;**
15. **ENCEPHALOMYELITIS;**
16. **HEADACHE;**
17. **GUILLAIN-BARRE SYNDROME;**
18. **DIFFICULTY BREATHING;**
19. **HEART ARRHYTHMIA;**
20. **MOTOR NEURON DISEASE;**
21. **PARALYSIS;**

1 **22. PREMATURE OVARIAN FAILURE;**

2 **23. SEIZURES;**

3 **24. SYNCOPE;**

4 **25. TRANSVERSE MYELITIS;**

5 **26. CELLULITIS; AND**

6 **27. IDIOPATHIC THROMBOCYTOPENIA; AND**

7 **(XV) ADVERSE EVENTS FOLLOWING HPV VACCINATION CAN**
8 **OCCUR MINUTES, HOURS, DAYS, WEEKS, OR MONTHS AFTER HPV VACCINATION.**

9 **(3) THE MARYLAND SUPPLEMENTAL INFORMATION SHEET**
10 **REQUIRED TO BE PROVIDED UNDER PARAGRAPH (1) OF THIS SUBSECTION SHALL**
11 **INCLUDE INFORMATION ON THE INDIVIDUAL'S RIGHTS IF THE INDIVIDUAL IS**
12 **HARMED BY AN HPV VACCINE, INCLUDING:**

13 **(I) THAT AN INDIVIDUAL WHO IS INJURED BY AN HPV VACCINE**
14 **CANNOT SUE THE PHARMACEUTICAL COMPANY OR THE PROVIDER OF THE HPV**
15 **VACCINE;**

16 **(II) CONTACT INFORMATION FOR THE NATIONAL VACCINE**
17 **INJURY COMPENSATION PROGRAM;**

18 **(III) THAT THERE IS NO GUARANTEE OF COMPENSATION EVEN IF**
19 **AN INDIVIDUAL SUFFERS HARM FROM AN HPV VACCINE;**

20 **(IV) THE TIME LIMIT FOR FILING A SUIT AGAINST A HEALTH**
21 **CARE PROVIDER, AS PROVIDED IN § 5-109 OF THE COURTS ARTICLE; AND**

22 **(V) THAT THE INDIVIDUAL MAY FILE A COMPLAINT WITH THE**
23 **DEPARTMENT.**

24 **(B) (1) A HEALTH CARE PROVIDER SHALL OBTAIN THE WRITTEN**
25 **CONSENT OF AN INDIVIDUAL OR THE INDIVIDUAL'S PARENT OR GUARDIAN ON A**
26 **MARYLAND HPV VACCINE CONSENT FORM DEVELOPED BY THE DEPARTMENT:**

27 **(I) BEFORE THE ADMINISTRATION OF A MARYLAND HPV**
28 **VACCINE; AND**

1 (II) AFTER FULFILLING THE REQUIREMENTS OF SUBSECTION
2 (A) OF THIS SECTION.

3 (2) THE MARYLAND HPV VACCINE CONSENT FORM SHALL INCLUDE:

4 (I) THE NAME, ADDRESS, AND CONTACT INFORMATION FOR
5 THE INDIVIDUAL OR THE INDIVIDUAL'S PARENT OR GUARDIAN;

6 (II) THE PROVIDER'S NAME AND LICENSE NUMBER, AND THE
7 NAME, ADDRESS, AND CONTACT NUMBER OF THE FACILITY WHERE THE HPV
8 VACCINE WAS ADMINISTERED;

9 (III) THE DATE ON WHICH THE HPV VACCINE WAS
10 ADMINISTERED;

11 (IV) THE NAME, LOT NUMBER, AND MANUFACTURER OF THE
12 HPV VACCINE ADMINISTERED;

13 (V) A STATEMENT THAT THE INDIVIDUAL OR THE INDIVIDUAL'S
14 PARENT OR GUARDIAN HAS BEEN INFORMED BY THE PROVIDER THAT THEY HAVE A
15 RIGHT TO DECLINE ANY HPV VACCINE;

16 (VI) A STATEMENT THAT THE INDIVIDUAL HAS RECEIVED A
17 COPY OF THE MARYLAND SUPPLEMENTAL INFORMATION SHEET AND HAS HAD THE
18 OPPORTUNITY TO READ IT AND ASK QUESTIONS;

19 (VII) A STATEMENT THAT THE INDIVIDUAL HAS BEEN INFORMED
20 THAT THERE HAVE BEEN NO LONG-TERM HEALTH-OUTCOME STUDIES REGARDING
21 THE SAFETY OF CONCOMITANT VACCINATION;

22 (VIII) A STATEMENT THAT THE INDIVIDUAL UNDERSTANDS THAT
23 IF THE INDIVIDUAL OR THE INDIVIDUAL'S CHILD IS HARMED BY THE VACCINE, THEY
24 CANNOT SUE THE PROVIDER OR THE MANUFACTURER;

25 (IX) A STATEMENT THAT THE INDIVIDUAL UNDERSTANDS THAT
26 THERE IS NO GUARANTEE THAT BY RECEIVING THE VACCINE THE INDIVIDUAL OR
27 THE INDIVIDUAL'S CHILD WILL BE PROTECTED FROM THE DISEASE THE VACCINE IS
28 ALLEGED TO PREVENT; AND

29 (X) DATED SIGNATURES OF THE INDIVIDUAL, OR THE
30 INDIVIDUAL'S PARENT OR GUARDIAN, AND THE PROVIDER.

1 (C) A HEALTH CARE PROVIDER ACTING IN GOOD FAITH MAY NOT BE HELD
2 LIABLE IN ANY CAUSE OF ACTION FOR PROVIDING AN INDIVIDUAL OR AN
3 INDIVIDUAL'S PARENT OR GUARDIAN WITH THE MARYLAND SUPPLEMENTAL
4 INFORMATION SHEET UNDER SUBSECTION (A) OF THIS SECTION.

5 18-343.

6 (A) AT THE TIME OF ADMINISTRATION OF AN HPV VACCINE TO AN
7 INDIVIDUAL, A HEALTH CARE PROVIDER SHALL RECORD IN A PERMANENT RECORD
8 TO WHICH THE INDIVIDUAL OR THE INDIVIDUAL'S PARENT OR GUARDIAN SHALL
9 HAVE ACCESS ON REQUEST:

10 (1) THE DATE OF EACH VACCINATION;

11 (2) THE MANUFACTURER AND LOT NUMBER OF THE VACCINE USED
12 FOR EACH VACCINATION;

13 (3) ANY OTHER IDENTIFYING INFORMATION ON THE VACCINE USED;

14 (4) THE NAME AND TITLE OF THE HEALTH CARE PROVIDER; AND

15 (5) A COPY OF THE SIGNED MARYLAND HPV VACCINE CONSENT
16 FORM.

17 (B) A HEALTH CARE PROVIDER ACTING IN GOOD FAITH MAY NOT BE HELD
18 LIABLE IN ANY CAUSE OF ACTION FOR REPORTING AN INDIVIDUAL'S ADVERSE
19 REACTION TO AN HPV VACCINE TO THE VAERS.

20 18-344.

21 THE DEPARTMENT SHALL ADOPT REGULATIONS ESTABLISHING:

22 (1) THE CONTENT OF THE MARYLAND SUPPLEMENTAL INFORMATION
23 SHEET;

24 (2) THE CONTENT OF THE MARYLAND HPV VACCINE CONSENT
25 FORM;

26 (3) PROCEDURES TO DISTRIBUTE COPIES OF THE MARYLAND
27 SUPPLEMENTAL INFORMATION SHEET AND MARYLAND HPV VACCINE CONSENT
28 FORM IN MULTIPLE LANGUAGES;

29 (4) PROCEDURES TO NOTIFY PROVIDERS OF THE CONTENT OF THE

1 **MARYLAND SUPPLEMENTAL INFORMATION SHEET AND MARYLAND HPV VACCINE**
2 **CONSENT FORM; AND**

3 **(5) PROCEDURES PERIODICALLY TO REVISE AND UPDATE THE**
4 **INFORMATION REQUIRED UNDER § 18-342 OF THIS SUBTITLE.**

5 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
6 October 1, 2019.