

SENATE BILL 783

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9lr2076
CF 9lr3067

By: **Senator West**

Introduced and read first time: February 4, 2019

Assigned to: Finance

A BILL ENTITLED

1 AN ACT concerning

2 **Public Health – Human Papillomavirus Vaccine – Information and Informed**
3 **Consent**

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

17 BY adding to

18 Article – Health – General

19 Section 18–341 through 18–344 to be under the new part “Part VII. Human
20 Papillomavirus”

21 Annotated Code of Maryland

22 (2015 Replacement Volume and 2018 Supplement)

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

25 **Article – Health – General**

26 **18–340. RESERVED.**

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 **PART VII. HUMAN PAPILLOMAVIRUS.**

2 **18-341.**

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

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

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

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

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

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

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

26 **18-342.**

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

29 (I) PROVIDE TO THE INDIVIDUAL OR THE INDIVIDUAL'S
30 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;

30 4. HUMAN IMMUNODEFICIENCY VIRUS (HIV)

1 INFECTION;

2 5. A WEAKENED IMMUNE SYSTEM;

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

5 7. HORMONAL FACTORS;

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

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

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

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

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

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

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

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

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

28 2. IF AN INDIVIDUAL IS INFECTED WITH CERTAIN
29 STRAINS OF HPV AT THE TIME OF INOCULATION, THE INDIVIDUAL'S RISK OF
30 DEVELOPING CERVICAL CANCER MAY INCREASE BY APPROXIMATELY 44.6%;

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

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

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

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

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

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

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

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

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

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

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

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

30 (XIV) RISKS ASSOCIATED WITH HPV VACCINES INCLUDE:

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

31 **(C) A HEALTH CARE PROVIDER ACTING IN GOOD FAITH MAY NOT BE HELD**

1 LIABLE IN ANY CAUSE OF ACTION FOR PROVIDING AN INDIVIDUAL OR AN
2 INDIVIDUAL'S PARENT OR GUARDIAN WITH THE MARYLAND SUPPLEMENTAL
3 INFORMATION SHEET UNDER SUBSECTION (A) OF THIS SECTION.

4 18-343.

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

9 (1) THE DATE OF EACH VACCINATION;

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

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

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

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

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

19 18-344.

20 THE DEPARTMENT SHALL ADOPT REGULATIONS ESTABLISHING:

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

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

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

28 (4) PROCEDURES TO NOTIFY PROVIDERS OF THE CONTENT OF THE
29 MARYLAND SUPPLEMENTAL INFORMATION SHEET AND MARYLAND HPV VACCINE

1 CONSENT FORM; AND

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

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