

SENATE BILL 1186

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8lr3975
CF HB 1690

By: **Senator Brochin**

Introduced and read first time: February 21, 2018

Assigned to: Rules

A BILL ENTITLED

1 AN ACT concerning

2 **Public Health – Human Papillomavirus Vaccine – Information and Reporting**

3 FOR the purpose of requiring a health care provider to provide an individual or an
4 individual's parent or guardian with certain information on the human
5 papillomavirus (HPV) vaccine, to attempt to elicit certain information, and to obtain
6 written consent before administering an HPV vaccine; requiring the Maryland
7 Department of Health to adopt regulations establishing the form and content of
8 certain information and the content of a certain consent form; prohibiting a health
9 care provider from being held liable for providing certain information to certain
10 individuals or for reporting certain information to the Department; requiring a
11 health care provider to record in a certain permanent record certain information
12 after the administration of an HPV vaccine; requiring a health care provider to
13 record in a certain record and report certain information to the Department under
14 certain circumstances; requiring the Department to notify certain vaccine
15 manufacturers under certain circumstances; requiring the Department to establish
16 a system to collect certain data relating to an HPV vaccine and to revise and update
17 certain information on a certain basis; requiring the Department to report to the
18 Centers for Disease Control and Prevention certain information; prohibiting a
19 provision of law from requiring the administration of an HPV vaccine in certain
20 circumstances; prohibiting the administration of an HPV vaccine to an individual
21 from being required under certain circumstances; providing for the construction of
22 this Act; requiring the Department to adopt certain regulations; defining certain
23 terms; and generally relating to the human papillomavirus vaccine.

24 BY adding to

25 Article – Health – General

26 Section 18–340 through 18–344 to be under the new part “Part VII. Human
27 Papillomavirus”

28 Annotated Code of Maryland

29 (2015 Replacement Volume and 2017 Supplement)

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



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

3 **Article – Health – General**

4 **PART VII. HUMAN PAPILLOMAVIRUS.**

5 **18-340.**

6 (A) IN THIS PART THE FOLLOWING WORDS HAVE THE MEANINGS
7 INDICATED.

8 (B) “HEALTH CARE PROVIDER” MEANS A LICENSED HEALTH CARE
9 PROFESSIONAL, ORGANIZATION, OR INSTITUTION, WHETHER PUBLIC OR PRIVATE,
10 UNDER WHOSE AUTHORITY AN HPV VACCINE IS ADMINISTERED.

11 (C) “MAJOR ADVERSE REACTION” MEANS:

12 (1) ANY SERIOUS ILLNESS, DISABILITY, OR IMPAIRMENT OF MENTAL,
13 EMOTIONAL, BEHAVIORAL, OR PHYSICAL FUNCTIONING OR DEVELOPMENT, THE
14 FIRST MANIFESTATION OF WHICH APPEARS WITHIN 7 DAYS AFTER THE DATE OF
15 ADMINISTRATION OF AN HPV VACCINE AND FOR WHICH THERE IS REASONABLE
16 SCIENTIFIC OR MEDICAL EVIDENCE THAT AN HPV VACCINE CAUSES, OR
17 SIGNIFICANTLY CONTRIBUTES TO, THE REACTION; AND

18 (2) ANY OTHER REACTION THAT THE DEPARTMENT SPECIFIES IN
19 REGULATIONS AS A BASIS FOR NOT CONTINUING WITH HPV VACCINE
20 ADMINISTRATION.

21 (D) “HPV” MEANS THE HUMAN PAPILLOMAVIRUS.

22 (E) “HPV VACCINE” MEANS ANY VACCINE THAT CONTAINS MATERIALS
23 INTENDED TO PREVENT THE OCCURRENCE OF HPV, WHETHER OR NOT THE
24 MATERIALS ARE ADMINISTERED SEPARATELY OR IN CONJUNCTION WITH OTHER
25 MATERIALS INTENDED TO PREVENT THE OCCURRENCE OF OTHER DISEASES.

26 **18-341.**

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

29 (I) PROVIDE TO THE INDIVIDUAL OR THE INDIVIDUAL’S
30 PARENT OR GUARDIAN WRITTEN INFORMATION REGARDING HPV; AND

1 **(II) ATTEMPT TO ELICIT THE INFORMATION NECESSARY TO**
2 **DETERMINE WHETHER THE ADMINISTRATION MAY NOT BE REQUIRED UNDER §**
3 **18-344(B) OF THIS SUBTITLE.**

4 **(2) THE INFORMATION REQUIRED TO BE PROVIDED UNDER**
5 **PARAGRAPH (1) OF THIS SUBSECTION SHALL INCLUDE:**

6 **(I) THE FREQUENCY, SEVERITY, AND POTENTIAL LONG-TERM**
7 **EFFECTS OF HPV;**

8 **(II) POSSIBLE ADVERSE REACTIONS TO AN HPV VACCINE THAT**
9 **SHOULD BE BROUGHT TO THE IMMEDIATE ATTENTION OF THE HEALTH CARE**
10 **PROVIDER;**

11 **(III) A FORM LISTING SYMPTOMS TO BE MONITORED AND**
12 **INCLUDING PLACES WHERE INFORMATION CAN BE RECORDED TO ASSIST IN**
13 **REPORTING TO THE HEALTH CARE PROVIDER, THE LOCAL HEALTH OFFICER, AND**
14 **THE DEPARTMENT;**

15 **(IV) MEASURES THE INDIVIDUAL OR THE INDIVIDUAL'S PARENT**
16 **OR GUARDIAN SHOULD TAKE TO REDUCE THE RISK OF, OR TO RESPOND TO, ANY**
17 **MAJOR ADVERSE REACTION;**

18 **(V) EARLY WARNING SIGNS OR SYMPTOMS THAT THE**
19 **INDIVIDUAL OR THE INDIVIDUAL'S PARENT OR GUARDIAN SHOULD BE AWARE OF AS**
20 **POSSIBLE PRECURSORS TO A MAJOR ADVERSE REACTION;**

21 **(VI) WHEN AND TO WHOM THE INDIVIDUAL OR THE**
22 **INDIVIDUAL'S PARENT OR GUARDIAN SHOULD REPORT ANY MAJOR ADVERSE**
23 **REACTION; AND**

24 **(VII) THE INFORMATION SPECIFIED IN REGULATIONS UNDER §**
25 **18-344(A)(1) THROUGH (3) OF THIS SUBTITLE.**

26 **(3) THE INFORMATION REQUIRED TO BE PROVIDED UNDER**
27 **PARAGRAPH (1) OF THIS SECTION SHALL INCLUDE THE FOLLOWING INFORMATION**
28 **RELATING TO HPV AND HPV VACCINATIONS, INCLUDING:**

29 **(I) 1. THERE ARE MORE THAN 150 STRAINS OF HPV AND**
30 **WHILE MILLIONS OF AMERICANS ARE INFECTED WITH HPV, THE VIRUSES GO AWAY**
31 **WITHOUT ANY TREATMENT IN THE VAST MAJORITY OF CASES;**

32 **2. THE BODY'S OWN IMMUNE SYSTEM CLEARS**

1 APPROXIMATELY 90% TO 95%, OR 5.7 PER 100,000 CASES, OF HPV INFECTIONS
2 WITHIN 2 YEARS;

3 (II) 1. APPROXIMATELY 15 STRAINS OF HPV ARE
4 ASSOCIATED WITH CERVICAL CANCER AND ARE CLASSIFIED AS HIGH RISK;

5 2. IF AN INFECTION FROM A HIGH RISK STRAIN OF HPV
6 PERSISTS FOR DECADES WITHOUT TREATMENT, THE INFECTION COULD LEAD TO
7 CERVICAL CANCER;

8 3. CERTAIN HPV VACCINES MAY STIMULATE THE BODY
9 TO PRODUCE ANTIBODIES AGAINST SOME, BUT NOT ALL, HIGH RISK HPV STRAINS;

10 4. IT IS ASSUMED, BUT NOT PROVEN, THAT THE
11 INCREASED ANTIBODIES FROM AN HPV VACCINATION WILL PREVENT CANCERS
12 ASSOCIATED WITH HIGH RISK HPV STRAINS;

13 (III) CERTAIN STRAINS OF HPV MAY CONTRIBUTE TO AN
14 INCREASED RISK OF CERVICAL CANCER, HOWEVER OTHER RISK FACTORS NEED TO
15 BE PRESENT, INCLUDING:

16 1. SMOKING;

17 2. ALCOHOL CONSUMPTION;

18 3. FAMILY MEDICAL HISTORY;

19 4. HUMAN IMMUNODEFICIENCY VIRUS (HIV)
20 INFECTION;

21 5. A WEAKENED IMMUNE SYSTEM;

22 6. THE PRESENCE OF OTHER SEXUALLY TRANSMITTED
23 INFECTIONS; AND

24 7. HORMONAL FACTORS;

25 (IV) 1. THE STATISTICAL LIKELIHOOD OF DEVELOPING
26 CERVICAL CANCER IS LESS THAN 1% FOR INDIVIDUALS WITH AN AVERAGE AGE OF
27 49 YEARS OLD;

28 2. THE DEATH RATE FOR CERVICAL CANCER IN THE
29 UNITED STATES IS 1.7 PER 100,000;

1 (v) 1. MOST CERVICAL CANCER IS PREVENTABLE AND
2 TREATABLE WITH PAP SCREENING;

3 2. EVEN IF AN INDIVIDUAL RECEIVES AN HPV VACCINE,
4 THE INDIVIDUAL SHOULD RECEIVE REGULAR PAP SCREENS BECAUSE THE HPV
5 VACCINE DOES NOT PREVENT ALL HIGH RISK STRAINS OF HPV WHICH MAY CAUSE
6 CERVICAL CANCER;

7 (vi) THE EFFECTIVENESS OF AN HPV VACCINE IS UNKNOWN,
8 AND SOME INDIVIDUALS SHOW NO MEASURABLE HPV ANTIBODIES 5 YEARS
9 POST-INJECTION;

10 (vii) AN HPV VACCINE MUST BE ADMINISTERED BEFORE AN
11 INDIVIDUAL IS EXPOSED TO HPV BECAUSE:

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

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

17 (viii) 1. THE MOST EFFECTIVE WAYS TO PREVENT HPV
18 INFECTION ARE ABSTINENCE AND LIFELONG MONOGAMY;

19 2. CONDOMS REDUCE THE RISK OF HPV INFECTION,
20 BUT DO NOT PROVIDE COMPLETE PROTECTION;

21 (ix) 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 (x) 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;

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

31 (xi) RISKS ASSOCIATED WITH HPV VACCINES INCLUDE:

- 1 1. **IDIOPATHIC THROMBOCYTOPENIA;**
- 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. DEATH.**

7 **(4) THE INFORMATION REQUIRED TO BE PROVIDED UNDER**
8 **PARAGRAPH (1) OF THIS SECTION SHALL INCLUDE THE INDIVIDUAL'S RIGHTS IF THE**
9 **INDIVIDUAL IS HARMED BY AN HPV VACCINATION, INCLUDING:**

10 **(i) THAT AN INDIVIDUAL WHO IS INJURED BY AN HPV VACCINE**
11 **CANNOT SUE THE PHARMACEUTICAL COMPANY OR THE PROVIDER OF THE HPV**
12 **VACCINE;**

13 **(ii) THE CURRENT CONTACT INFORMATION FOR THE NATIONAL**
14 **VACCINE INJURY COMPENSATION PROGRAM;**

15 **(iii) THAT THERE IS NO GUARANTEE OF COMPENSATION EVEN IF**
16 **AN INDIVIDUAL SUFFERS HARM FROM AN HPV VACCINE;**

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

19 **(v) THAT THE INDIVIDUAL MAY FILE A COMPLAINT WITH THE**
20 **MARYLAND DEPARTMENT OF HEALTH.**

21 **(B) AFTER FULFILLING THE REQUIREMENTS OF SUBSECTION (A) OF THIS**
22 **SECTION, A HEALTH CARE PROVIDER SHALL OBTAIN THE WRITTEN CONSENT OF THE**
23 **INDIVIDUAL OR THE INDIVIDUAL'S PARENT OR GUARDIAN BEFORE THE**
24 **ADMINISTRATION OF AN HPV VACCINE.**

25 **(C) THE DEPARTMENT SHALL ADOPT REGULATIONS ESTABLISHING:**

26 **(1) A FORM FOR THE INFORMATION TO BE PROVIDED TO THE**
27 **INDIVIDUAL OR THE INDIVIDUAL'S PARENT OR GUARDIAN UNDER SUBSECTION (A)**
28 **OF THIS SECTION; AND**

1 **(2) THE WRITTEN CONSENT FORM REQUIRED UNDER SUBSECTION (B)**
2 **OF THIS SECTION.**

3 **(D) A HEALTH CARE PROVIDER ACTING IN GOOD FAITH MAY NOT BE HELD**
4 **LIABLE IN ANY CAUSE OF ACTION FOR PROVIDING AN INDIVIDUAL OR AN**
5 **INDIVIDUAL'S PARENT OR GUARDIAN WITH THE INFORMATION UNDER SUBSECTION**
6 **(A) OF THIS SECTION.**

7 **18-342.**

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

12 **(1) THE DATE OF EACH VACCINATION;**

13 **(2) THE MANUFACTURER AND LOT NUMBER OF THE VACCINE USED**
14 **FOR EACH VACCINATION;**

15 **(3) ANY OTHER IDENTIFYING INFORMATION ON THE VACCINE USED;**
16 **AND**

17 **(4) THE NAME AND TITLE OF THE HEALTH CARE PROVIDER.**

18 **(B) (1) WITHIN 24 HOURS OF ADMINISTERING AN HPV VACCINE, A**
19 **HEALTH CARE PROVIDER WHO HAS ADMINISTERED AN HPV VACCINE TO AN**
20 **INDIVIDUAL AND HAS REASON TO BELIEVE THAT THE INDIVIDUAL HAS HAD A MAJOR**
21 **ADVERSE REACTION TO THE VACCINE SHALL:**

22 **(I) RECORD ALL RELEVANT INFORMATION IN THE**
23 **INDIVIDUAL'S PERMANENT MEDICAL RECORD; AND**

24 **(II) REPORT THE INFORMATION, INCLUDING THE**
25 **MANUFACTURER'S NAME AND LOT NUMBER, TO THE LOCAL HEALTH OFFICER, WHO**
26 **SHALL IMMEDIATELY FORWARD THE INFORMATION TO THE DEPARTMENT.**

27 **(2) ON RECEIPT OF THE INFORMATION REQUIRED UNDER**
28 **PARAGRAPH (1)(II) OF THIS SUBSECTION, THE DEPARTMENT SHALL IMMEDIATELY**
29 **NOTIFY THE VACCINE MANUFACTURER.**

30 **(C) A HEALTH CARE PROVIDER ACTING IN GOOD FAITH MAY NOT BE HELD**
31 **LIABLE IN ANY CAUSE OF ACTION FOR REPORTING AN INDIVIDUAL'S MAJOR**

1 ADVERSE REACTION TO AN HPV VACCINE TO THE DEPARTMENT.

2 18-343.

3 (A) THE DEPARTMENT SHALL ADOPT REGULATIONS ESTABLISHING A
4 SYSTEM TO COLLECT DATA FROM LOCAL HEALTH OFFICERS, HEALTH CARE
5 PROVIDERS, AND PARENTS ON THE INCIDENCE OF HPV AND MAJOR ADVERSE
6 REACTIONS TO AN HPV VACCINE.

7 (B) ON THE BASIS OF INFORMATION COLLECTED UNDER THIS SECTION AND
8 FROM OTHER INFORMATION AVAILABLE, THE DEPARTMENT PERIODICALLY SHALL
9 REVISE AND UPDATE THE INFORMATION REQUIRED BY § 18-341 OF THIS SUBTITLE
10 AND THE REGULATIONS ADOPTED UNDER § 18-344 OF THIS SUBTITLE.

11 (C) THE DEPARTMENT SHALL REPORT TO THE CENTERS FOR DISEASE
12 CONTROL AND PREVENTION ANY INFORMATION COLLECTED UNDER SUBSECTION
13 (A) OF THIS SECTION AND ANY INFORMATION RECEIVED UNDER § 18-342(B) OF THIS
14 SUBTITLE.

15 18-344.

16 (A) THE DEPARTMENT SHALL ADOPT REGULATIONS SPECIFYING:

17 (1) THE CIRCUMSTANCES UNDER WHICH AN HPV VACCINE SHOULD
18 NOT BE ADMINISTERED;

19 (2) THE CIRCUMSTANCES UNDER WHICH ADMINISTRATION OF AN
20 HPV VACCINE SHOULD BE DELAYED;

21 (3) ANY CATEGORIES OF POTENTIAL RECIPIENTS OF AN HPV
22 VACCINE WHO ARE SIGNIFICANTLY MORE VULNERABLE TO MAJOR ADVERSE
23 REACTIONS THAN THE GENERAL POPULATION; AND

24 (4) PROCEDURES TO NOTIFY PHYSICIANS OF THE CONTENT OF THE
25 REGULATIONS.

26 (B) THE ADMINISTRATION OF AN HPV VACCINE TO AN INDIVIDUAL MAY
27 NOT BE REQUIRED BY ANY PROVISION OF LAW IF, IN THE PHYSICIAN'S MEDICAL
28 JUDGMENT:

29 (1) THE CIRCUMSTANCES SPECIFIED IN REGULATIONS UNDER
30 SUBSECTION (A)(1) OR (2) OF THIS SECTION ARE PRESENT; OR

1 **(2) TAKING INTO ACCOUNT THE CATEGORIES SPECIFIED IN**
2 **REGULATIONS UNDER SUBSECTION (A)(3) OF THIS SECTION AND ANY OTHER**
3 **RELEVANT INFORMATION, THE RISK TO THE POTENTIAL RECIPIENT OUTWEIGHS**
4 **THE BENEFITS TO BOTH THE POTENTIAL RECIPIENT AND THE PUBLIC IN**
5 **ADMINISTERING THE VACCINE.**

6 **(C) NOTHING IN THIS PART MAY BE CONSTRUED TO AFFECT ANY**
7 **EMERGENCY AUTHORITY OF THE SECRETARY UNDER ANY OTHER PROVISION OF**
8 **LAW TO PROTECT THE PUBLIC HEALTH.**

9 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
10 October 1, 2018.