

Department of Legislative Services
 Maryland General Assembly
 2019 Session

FISCAL AND POLICY NOTE
First Reader

Senate Bill 783 (Senator West)
 Education, Health, and Environmental Affairs

Public Health - Human Papillomavirus Vaccine - Information and Informed Consent

This bill requires a health care provider, prior to administering a human papillomavirus (HPV) vaccine, to (1) provide an individual or the individual’s parent or guardian with a “Maryland supplemental information sheet” and (2) obtain a signed Maryland HPV vaccine consent form. The bill also establishes required recordkeeping for the administration an HPV vaccine. The Maryland Department of Health (MDH) must adopt implementing regulations, as specified.

Fiscal Summary

State Effect: General fund expenditures increase by at least \$58,300 in FY 2020 for contractual staff. Future years reflect termination of the contractual position in FY 2021. Revenues are not affected.

(in dollars)	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024
Revenues	\$0	\$0	\$0	\$0	\$0
GF Expenditure	58,300	16,700	0	0	0
Net Effect	(\$58,300)	(\$16,700)	\$0	\$0	\$0

Note: () = decrease; GF = general funds; FF = federal funds; SF = special funds; - = indeterminate increase; (-) = indeterminate decrease

Local Effect: Any impact on local health departments from the requirement to obtain written consent and provide an information sheet prior to administering an HPV vaccine is expected to be minimal. Local revenues are not affected.

Small Business Effect: Minimal.

Analysis

Bill Summary: A “Maryland supplemental information sheet” means a document that provides a potential HPV vaccine recipient (or their parent or guardian) with additional information that is necessary for making an informed decision whether or not to consent to inoculations with an HPV vaccine.

A Maryland supplemental information sheet must include, at a minimum, a number of statements relating to HPV and HPV vaccines. Among other things, the required information must include how HPV is spread, health risks related to HPV, statistics about HPV, how and what HPV vaccines are and should be administered, when HPV vaccines are effective, information about the Gardasil 9 vaccine, who is recommended to receive HPV vaccines, risks associated with HPV vaccines, information on adverse events following vaccination, and an individual’s rights if harmed by an HPV vaccine.

MDH must develop a consent form upon which a health care provider must obtain written consent prior to administering an HPV vaccine in the State. Among other things, the consent form must include demographic information for the patient, specified information about the HPV vaccine administered, statements regarding HPV vaccines, and dated signatures from the individual and the individual’s parents or guardians, and the provider.

At the time of administration of an HPV vaccine, a health care provider must record in a permanent record to which the individual who received the vaccine (or their parent or guardian) must have access on request, specified information about the vaccine administered and its administration.

A health care provider acting in good faith cannot be held liable for any cause of action for providing an individual or the individual’s parent or guardian with the Maryland supplemental sheet required under the bill. In addition, a health care provider acting in good faith may not be held liable in any cause of action for reporting an individual’s adverse reaction to an HPV vaccine to the National Vaccine Adverse Event Surveillance Program, which is administered by the U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration.

MDH must adopt implementing regulations that establish (1) the content of the supplemental information sheet; (2) the content of the Maryland HPV vaccine consent form; (3) procedures to distribute copies of the supplemental information sheet and the HPV vaccine consent form in multiple languages; (4) procedures to notify providers of the content of the information sheet and the consent form; and (5) procedures to periodically revise and update the required information on the information sheet and HPV vaccine consent form.

Current Law/Background:

Advisory Committee on Immunization Practices

CDC sets the U.S. childhood immunization schedule based on recommendations from the Advisory Committee on Immunization Practices (ACIP). ACIP comprises medical and public health experts who develop recommendations on the use of vaccines in the civilian population of the United States. The recommendations stand as public health guidance for the safe use of vaccines and related biological products. ACIP gathers necessary clinical and epidemiological information and develops and updates guidance on who should and should not receive vaccines, circumstances in which vaccination should be delayed, and categories of vaccine recipients who are significantly more vulnerable to major adverse reactions.

MDH's Prevention and Health Promotion Administration notes that some of the information required under the bill is duplicative, and in some cases, contradictory to information provided by ACIP regarding the HPV vaccine.

Vaccine Information Statements

The National Childhood Vaccine Injury Act (42 U.S.C. § 300aa-26) requires all health care providers in the United States who administer any of a specified list of vaccines, including for HPV, to provide a copy of the vaccine information statement (VIS) produced by CDC to the patient or the patient's parent or guardian prior to administration of the vaccine. A VIS should be supplemented with visual presentations or oral explanations as appropriate.

Human Papillomavirus

According to CDC, HPV is the most common sexually transmitted infection. Nearly 80 million Americans are currently infected with HPV, and about 14 million people become newly infected each year. Almost every person who is sexually active will get HPV at some time in their life if they do not get the HPV vaccine. There are many different types of HPV, some of which can cause genital warts and cancer. There are HPV tests to screen for HPV-related cancers in women.

CDC recommends that children aged 11 to 12 get the recommended series of HPV vaccine to protect against cancers caused by HPV. Additionally, CDC recommends catch-up vaccines for boys and men through age 21 and for girls and women through age 26, if they did not get vaccinated when they were younger. The HPV vaccine is *not* part of the current immunization requirements for children entering school in Maryland.

State Expenditures: MDH advises that general fund expenditures increase by \$140,279 in fiscal 2020, and at least \$179,761 annually thereafter to hire one full-time physician clinical specialist to develop and provide the required information sheet and consent form to health providers in the State, promulgate regulations, and gather clinical and epidemiological information in out-years to develop and update the required information.

While the Department of Legislative Services (DLS) agrees that the bill establishes additional responsibilities that cannot be absorbed by existing staff, DLS advises that the bulk of the added responsibilities incurred by the bill can be completed in the first year of implementation; thereafter, less effort is required.

Thus, MDH general fund expenditures increase by at least \$58,279 in fiscal 2020, which accounts for the bill's October 1, 2019 effective date. This estimate reflects the cost of hiring one part-time (50%) contractual physician clinical specialist to develop the required information sheet and consent form, promulgate regulations, and distribute the information to health care providers. It includes a salary, fringe benefits, one-time start-up costs, and ongoing operating expenses.

Contractual Position	0.5
Salary and Fringe Benefits	\$53,154
Operating Expenses	<u>5,125</u>
Total FY 2020 State Expenditures	\$58,279

As the bill requires that MDH establish procedures to distribute copies of the supplemental information sheet and informed consent form in multiple languages, expenditures increase by an additional but likely minimal amount to translate the forms. Actual costs depend on the final word count of each form and the number of languages into which the forms are translated.

Future year expenditures reflect termination of the contractual employee in fiscal 2021. Given the publically available information and programs in place to track vaccines and provide patient information, it is assumed that MDH can update the consent form and information sheet with existing budgeted staff and resources in future years.

This estimate does not include any health insurance costs that could be incurred for specified contractual employees under the State's implementation of the federal Patient Protection and Affordable Care Act.

Additional Information

Prior Introductions: SB 1186 of 2018, a similar bill, was referred to the Senate Rules Committee, but no further action was taken. Its cross file, HB 1690 was referred to the House Rules and Executive Nominations Committee, but no further action was taken.

Cross File: HB 1332 (Delegate Szeliga) - Rules and Executive Nominations.

Information Source(s): Maryland Department of Health; U.S. Centers for Disease Control and Prevention; Department of Legislative Services

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an/jc

Analysis by: Kathleen P. Kennedy

Direct Inquiries to:
(410) 946-5510
(301) 970-5510