

Department of Legislative Services
Maryland General Assembly
2023 Session

FISCAL AND POLICY NOTE
First Reader

House Bill 1161 (Delegate Szeliga, *et al.*)
Health and Government Operations

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

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 Maryland Department of Health (MDH) must adopt implementing regulations, as specified.

Fiscal Summary

State Effect: MDH can implement the bill with existing budgeted resources. Revenues are not affected.

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, the following information concerning HPV and HPV vaccines: (1) a statement that HPV is a very common viral infection that is transmitted primarily through sexual contact; (2) a list of 27 health risks that are associated with HPV; (3) an acknowledgement that adverse events following HPV vaccination can occur minutes, hours, days, weeks, or months after HPV vaccination; and (4) a disclosure specifying an individual's rights if the individual is harmed by an HPV vaccine.

MDH must develop a consent form upon which a health care provider must obtain written consent from an individual (or their parent or guardian) prior to administering an HPV vaccine in the State. The consent form must include statements that the individual (1) has been informed by the provider that the individual (or their parent or guardian) has a right to decline any HPV vaccine; (2) has received a copy of the Maryland supplemental information sheet and has had the opportunity to read it and ask questions; (3) has been informed that there have been no long-term health outcome studies regarding the safety of concomitant vaccination; (4) understands that if the individual or the individual's child is harmed by the vaccine, the individual cannot sue the provider or the manufacturer; and (5) understands there is no guarantee that by receiving the vaccine the individual will be protected from the disease the vaccine is alleged to prevent. The consent form must also include dated signatures of the individual (or their parent or guardian) and the provider.

A health care provider acting in good faith cannot be held liable for any cause of action for providing an individual (or their parent or guardian) with the Maryland supplemental sheet required under the bill.

MDH must adopt implementing regulations that establish (1) the content of the Maryland 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 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 consent form.

Current Law:

Vaccine Information Statements

The National Childhood Vaccine Injury Act (42 U.S.C. § 300aa-26) requires all health care providers who administer any of a specified list of vaccines, including for HPV, to provide a copy of the vaccine information statement (VIS) produced by the U.S. Centers for Disease Control (CDC) to the patient or the patient's parent or guardian prior to administration of the vaccine. A VIS must be presented in understandable terms and include a concise description of the benefits and risks associated with the vaccine, a

statement of the availability of the National Vaccine Injury Compensation Program, and any other relevant information. A VIS should be supplemented with visual presentations or oral explanations as appropriate.

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.

Additional Comments: According to CDC, HPV infections are very common. Most HPV infections go away on their own within two years. However, sometimes HPV infections will last longer and cause some cancers, including cancers of the cervix, vagina, vulva, penis, anus, and throat. 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 children and adults 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.

MDH notes that some of the information required under the bill is duplicative, and in some instances, contradictory to the information provided by ACIP regarding the HPV vaccine. MDH advises that it expects to receive a significant number of calls from patients and providers who are confused by the different language and tenor of the Maryland supplemental information sheet and the VIS.

Additional Information

Prior Introductions: Similar legislation has not been introduced within the last three years.

Cross File: None.

Information Source(s): Maryland Department of Health; Department of Legislative Services

Fiscal Note History: First Reader - March 10, 2023
km/jc

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