



Telephone: (517) 373-5383 Fax: (517) 373-1986 TDD: (517) 373-0543

Senate Bills 1416 and 1417 (as reported without amendment)

Sponsor: Senator Bev Hammerstrom

Committee: Health Policy

Date Completed: 9-18-06

RATIONALE

In June 2006, the U.S. Food and Drug Administration (FDA) announced its approval of the first vaccine developed to prevent cervical cancer, precancerous lesions, and genital warts due to four types of the human papillomavirus (HPV), which is the most common sexually transmitted infection in the United States. According to the Centers for Disease Control and (CDC), Prevention the vaccine recommended for 11- to 12-year old girls, and may be given to girls as young as nine. It also is recommended for 13- to 26-year old females who have not received or completed three-injection the Ideally, according to the CDC, females should be vaccinated before they become sexually active, because the vaccine is most effective in girls and women who have not yet acquired any of the four types of HPV covered by the vaccine. In light of the FDA's approval of the vaccine, many people believe that State law should require 6thgrade girls to be vaccinated, unless their parents or guardians object.

CONTENT

Senate Bills 1416 and 1417 would amend the Public Health Code and the Revised School Code, respectively, to do the following:

- -- Require the Department of Community Health (DCH) to identify materials containing information about the risks associated with the human papillomavirus and cervical cancer, and about the HPV vaccine.
- -- Require the DCH to inform schools of the availability of that information.

- -- Require the parent or guardian of a female 6th-grade student to give school officials a statement that she had received the HPV vaccine or that the parent or guardian chose not to have her vaccinated.
- Require the health care provider administering the HPV vaccine to provide a statement or certificate, or make an entry on a certificate.

Senate Bill 1417 is tie-barred to Senate Bill 1416.

Senate Bill 1416

The bill would require the DCH, by September 1, 2007, to identify materials containing information regarding the risks associated with HPV and cervical cancer, and the availability, effectiveness, and potential risks of the HPV vaccine. The Department would have to notify each school in the State of the availability of these materials and post them on the DCH website.

Under the Public Health Code, the health care provider administering an immunizing agent to a child must give a certificate of immunization to the person accompanying the child, or make an entry on a certificate in the person's possession. The bill would require the health care provider administering the HPV vaccine to do the same (although the provider could give either a statement or a certificate of that immunization).

Beginning with the 2008 school year, the parent, guardian, or person in loco parentis of a female child enrolling in 6th grade for the first time in a public or nonpublic school,

Page 1 of 4 sb1416&1417/0506

would have to submit to school officials one of the following:

- -- A statement signed by a physician that the child had received the HPV vaccine.
- -- A statement signed by the child's parent, guardian, or person in loco parentis to the effect that he or she had received the information on the connection between HPV and cervical cancer identified by the DCH, and had elected for the child not to receive the HPV vaccine.

The Code requires the DCH to promulgate rules to implement Part 92 (Immunizations). The DCH also must promulgate rules to implement the expansion of the Childhood Immunization Registry to include the reporting and recording of additional information such as lead screening performed on children. The bill also would require the inclusion of information on the administration of the HPV vaccine. (Under the Code, the DCH must establish the Registry to record information regarding immunizations performed under Part 92.)

Senate Bill 1417

Under the Public Health Code, a child enrolling in a public or nonpublic school for the first time or enrolling in 6th grade for the first time must submit one of the following:

- -- A statement signed by a physician that the child has been tested for and immunized or protected against diseases specified by the DCH Director.
- -- A statement signed by a parent or guardian to the effect that the child has not been immunized because of religious convictions or other objection to immunization.
- -- A statement signed by a physician certifying that the child is in the process of complying with all immunization requirements.

Under the bill, beginning with the 2008 school year, the parent or legal guardian of a female child enrolling in 6th grade for the first time in a public or nonpublic school, also would have to submit to school officials one of the following:

- -- A statement signed by a physician that the child had received the HPV vaccine.
- -- A statement signed by the child's parent or guardian to the effect that he or she

had received the information on the connection between HPV and cervical cancer identified by the DCH, and had elected for the child not to receive the HPV vaccine.

MCL 333.9206 et al. (S.B. 1416) 380.1177 (S.B. 1417)

BACKGROUND

<u>Humanpapillomvirus</u>

According to the Centers for Disease Control and Prevention:

"Genital HPV is a common virus that is passed on through genital contact, most often during vaginal and anal sex. About 40 types of HPV can infect the genital areas of men and women. While most HPV types cause no symptoms and go away on their own, some types can cause cervical cancer in women. These types also have been linked to other less common genital cancers... Other types of HPV can cause warts in the genital areas of men and women...

At least 50% of sexually active people will get HPV at some time in their lives. Every year in the United States (U.S.), about 6.2 million people get HPV. HPV is most common in young women and men who are in their late teens and early 20s...

The American Cancer Society estimates that in 2006, over 9,700 women will be diagnosed with cervical cancer and 3,700 women will die from this cancer in the U.S."

DCH Immunization Rules

Under Rule 325.176 of the Michigan Administrative Code, a child who is four through six years old and who is entering school must be in compliance with specified immunization requirements. These include a prescribed number of doses of a tetanus vaccine, pertussis vaccine, and polio vaccine. The child also must have evidence of measles immunity, mumps immunity, and rubella immunity as shown either through vaccinations or laboratory evidence, as well as evidence of varicella immunity as shown by a vaccination, lab evidence, or a parent, guardian, or physician statement that the child has had varicella disease. In addition,

a child must have three doses of hepatitis B vaccine or a laboratory finding of immunity.

Rule 325.176 also prescribes immunization requirements for a child who is seven through 18 years old and who is entering school or enrolled in 6th grade. These requirements are generally the same as those prescribed for four- to six-year-olds, except for some differences in the dosage requirements and the exclusion of pertussis.

The rule requires the administrator of a child's school, when presented with a medical, religious, or other exemption, to recognize the exemption status of the child.

ARGUMENTS

(Please note: The arguments contained in this analysis originate from sources outside the Senate Fiscal Agency. The Senate Fiscal Agency neither supports nor opposes legislation.)

Supporting Argument

The bills would save lives by requiring 6thgrade girls to be vaccinated against HPV. According to the FDA, the vaccine is effective against the two types of HPV that cause approximately 70% of cervical cancer, which is estimated to cause 3,700 deaths in the United States each year. The vaccine also is effective against the two types of HPV that cause approximately 90% of genital warts—something that both women and men can contract and pass on to their partners. Because the vaccine is most effective before a female becomes sexually active and acquires HPV, and is recommended for 11and 12-year-old girls, it would make sense for girls to be vaccinated before they begin 6th grade. State law already requires 6th graders to be vaccinated against, or have immunity to, a number of other serious diseases. Considering the effectiveness of the newly approved HPV vaccine to prevent cervical cancer, Michigan should add this vaccine to those already mandated. As the law allows for those vaccines, however, the bills would permit parents and guardians to opt out of having 6th-grade girls vaccinated for HPV, on religious, philosophical, or other grounds.

In addition, the bills would ensure that information about HPV and the vaccine was available to parents and guardians, by requiring the DCH to identify related materials, notify schools of their availability, and post them on its website. Many parents

may not be aware of the risks and prevalence of HPV or the availability of the vaccine, and might believe that their daughters do not need to be vaccinated because they are not sexually active. The required materials would help parents make an informed decision about whether to have 6th-grade girls immunized.

Opposing Argument

Despite the provisions allowing parents and quardians to choose not to have 6th graders vaccinated, some have expressed concern that the bills could interfere with parental rights and send a message that underage sex is okay ("State law on vaccinations for HPV would infringe on family", Oakland Press, 9-14-06). Unlike mumps and other contagious diseases, HPV is not transmitted casually or through indirect contact in public places such as schools. Thus, children need not be inoculated against HPV to prevent an outbreak. Also, the CDC reports that the retail cost of the HPV vaccine is \$120 per dose (\$360 for the full series). expense would be an imposition on families who do not have health insurance or whose insurance does not cover the HPV vaccine.

Response: Cervical cancer can mean a death sentence to some girls who do not receive the HPV vaccine, which most people would agree is an excessive penalty for underage sex. Parents or guardians who did not want their daughters or wards to be vaccinated simply would have to submit a statement to that effect.

As to the monetary cost, according to the CDC, Federal health programs such as Vaccines for Children (VCF) will cover the HPV vaccine. The VCF program provides free vaccines for children and teens under 19 years old, who are uninsured, Medicaideligible, American Indian, or Alaska Native. The program also allows children and teens to get a VCF vaccine through Federally Qualified Health Centers or Rural Health Centers, if their private insurance does not cover the vaccine. Furthermore, the price of the vaccine could be far less than the cost of future medical treatment, especially for a serious condition such as cancer.

Legislative Analyst: Suzanne Lowe

FISCAL IMPACT

Senate Bill 1416

Provision of the HPV vaccine is estimated to cost between \$300 and \$400 per recipient. It is likely that enactment of the bill would significantly increase the number of individuals receiving the HPV vaccine, creating an indeterminate increase in cost to the Medicaid program and to health benefits provided for State and local employees. The Department of Community Health also could see a slight increase in administrative cost associated with modifying the Department's and Childhood Immunization Registry to meet the requirements in this bill.

Senate Bill 1417

The bill would have no fiscal impact on State or local government.

Fiscal Analyst: David Fosdick Kathryn Summers-Coty

A0506\s1416a

This analysis was prepared by nonpartisan Senate staff for use by the Senate in its deliberations and does not constitute an official statement of legislative intent.