



Senate Fiscal Agency  
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BILL ANALYSIS

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Senate Bill 415 (Substitute S-1 as reported)  
Senate Bill 416 (as reported without amendment)  
Sponsor: Senator Deborah Cherry (S.B. 415)  
Senator Tony Stamas  
Committee: Health Policy

Date Completed: 5-23-07

### **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 genital lesions, and genital warts due to four types of human papillomavirus (HPV), which is the most common sexually transmitted infection in the United States. The vaccine, which is called Gardasil and is manufactured by Merck, is recommended for 11- to 12-year old girls, and may be given to girls as young as nine, according to the Centers for Disease Control and Prevention (CDC). It also is recommended for 13- to 26-year old females who have not received or completed the three-injection series. 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 prevalence of the virus and the FDA's approval of the vaccine, many people believe that the State and schools should take steps to make parents of schoolchildren aware of HPV and the vaccine, and the potential risks of each.

### **CONTENT**

**Senate Bill 415 (S-1) would amend the Public Health Code to require the Department of Community Health (DCH) to identify materials about human papillomavirus and immunization for it, notify schools of the availability of the materials, and encourage schools to make the information available to parents.**

**Senate Bill 416 would amend the Revised School Code to require a school board to include information about HPV and the HPV vaccine if the board provided information on school health issues to the parents of students in or entering the 6th grade.**

The bills are described below in further detail.

#### **Senate Bill 415 (S-1)**

The bill would require the DCH to identify materials that contained information regarding the risks associated with HPV and the availability, effectiveness, and potential risks of immunization for HPV. The DCH would have to notify each public school, public school academy, and nonpublic school in the State of the availability of the materials and would have to post them on its website.

The DCH would have to encourage each public school, public school academy, and nonpublic school to provide the information or make it available to parents of students attending the school.

#### **Senate Bill 416**

Under the bill, if, at the beginning of a school year, the board of a school district or board of directors of a public school academy provided information on immunizations, infectious disease, medication, or other school health issues to parents and guardians of pupils in or entering grade 6, the board would have to

include information about HPV and the HPV vaccine. At a minimum, the information would have to include the risks associated with HPV; the availability, effectiveness, and potential risks of immunization for HPV; and sources where parents and guardians could obtain additional information about HPV and could obtain vaccination of a child against HPV.

Proposed MCL 333.9205b (S.B. 415)  
MCL 380.1177a (S.B. 416)

## **BACKGROUND**

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 CDC also has reported that an estimated 11,100 new cases of cervical cancer will be diagnosed and approximately 3,700 women will die from the disease during 2007.

According to the FDA, "Four studies, one in the United States and three multinational, were conducted in 21,000 women to show how well Gardasil worked in women between the ages of 16 and 26 by giving them either the vaccine or placebo. The results showed that in women who had not already been infected, Gardasil was nearly 100 percent effective in preventing precancerous cervical lesions, precancerous vaginal and vulvar lesions, and genital warts caused by infection with the HPV types against which the vaccine is directed. While the study period was not long enough for cervical cancer to develop, the prevention of these cervical precancerous lesions is believed

highly likely to result in the prevention of those cancers..."

Two studies were also performed to measure the immune response to the vaccine among younger females aged 9-15 years. Their immune response was as good as that found in 16-26 year olds, indicating that the vaccine should have similar effectiveness when used in the 9-15 year age group.

The safety of the vaccine was evaluated in approximately 11,000 individuals. Most adverse experiences in study participants who received Gardasil included mild or moderate local reactions, such as pain or tenderness at the site of injection."

A second vaccine, which is called Cervarix and targets the two strains of HPV that cause cervical cancer, has been developed by GlaxoSmithKline and is awaiting FDA approval.

## **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**

Despite the prevalence of HPV and the availability of the vaccine for it, there is anecdotal evidence that relatively few girls are being vaccinated. For example, according to an article in the *Detroit Free Press* (3-20-07), in mid-March, the Macomb County Health Department still had 682 of the 1,600 doses it ordered last fall, which were earmarked for females 18 and younger through the Medicaid program for poor children. The department had administered 256 doses and sent 662 to area physicians who requested them. The department also still had 47 of the 90 additional doses it had purchased for non-Medicaid patients.

While girls and their parents might be making a decision against vaccination, it is possible that they do not know about the virus, how it is transmitted, the infections and diseases it can lead to, that a vaccine is available to prevent cervical cancer caused by HPV, or the risks associated with vaccination. Although clinical studies of Gardasil showed minimal adverse effects, many people remain concerned about potential long-term effects, as well as the long-term efficacy of the vaccine. Another

consideration is the cost of vaccination, which totals at least \$360 for the three-dose series. While some insurers may cover the cost, many families do not have health insurance. Also, although Federal health programs will cover the HPV vaccine for some uninsured children and teens, that coverage is available only if funds are appropriated.

Without adequate information, parents cannot make an informed decision about whether to have their daughters vaccinated, or even whether to have a discussion with preteen girls about a sexually transmitted disease. The bills would require materials about HPV and the vaccine to be posted on the DCH website, would encourage schools to provide the information to parents, and would require schools to include the information with other health-related information given to parents of 6th-graders. These measures would respect the authority of parents to make decisions about their children's health, while helping to ensure that those decisions were made knowledgeably.

#### **Supporting Argument**

Senate Bill 416 would be consistent with existing requirements concerning a common strain of bacterial meningitis. Under Section 1177a of the Revised School Code, if a school board provides information on immunizations, infectious disease, medications, or other school health issues to parents and guardians of pupils in at least grades 6, 9, and 12, the board also must provide information about meningococcal meningitis and the vaccine for it, including information about how the disease is spread and where parents and guardians may have a child vaccinated against it. The Department of Education must make information meeting these requirements available to school districts, public school academies, and nonpublic schools. Public Act 240 of 2005 added Section 1177a to the Code, in order to educate parents about a potentially serious illness, enabling them to take action to prevent their children from being infected as well as slow the spread of the disease. Senate Bill 416 would take the same approach for HPV.

Legislative Analyst: Suzanne Lowe

#### **FISCAL IMPACT**

##### **Senate Bill 415 (S-1)**

Enactment of the bill would lead to an indeterminate increase in administrative cost for the Department of Community Health associated with researching educational materials about HPV and HPV immunization and notifying schools of the availability of the information.

##### **Senate Bill 416**

The bill would have no fiscal impact on State government.

School districts providing other health information to families of 6th graders would see minimally increased costs pertaining to the compilation and distribution of information on HPV.

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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.