



Senate Fiscal Agency
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BILL ANALYSIS

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Senate Bill 415 (as enacted)
House Bill 5322 (as enacted)
Sponsor: Senator Deborah Cherry (S.B. 415)
Representative Brenda Clark (H.B. 5322)
Senate Committee: Health Policy
House Committee: Health Policy

PUBLIC ACT 120 of 2008
PUBLIC ACT 121 of 2008

Date Completed: 6-5-08

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.

House Bill 5322 amended the Revised School Code to require a school board to include information about HPV and the HPV vaccine if the board provides information on other health issues to the parents of students in at least the 6th, 9th, and 12th grades.

The bills took effect on May 9, 2008.

Senate Bill 415

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

The DCH also must 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.

CONTENT

Senate Bill 415 amended 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.

House Bill 5322

Under the bill, if the board of a school district or board of directors of a public school academy, at the beginning of a school year, 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, then the board must

include information about HPV and the vaccine for HPV. The information must include at least the following:

- The risks associated with HPV.
- The availability, effectiveness, and potential risks of immunization for HPV.
- Sources where parents and guardians may obtain additional information about HPV and may obtain vaccination of a child against HPV.

The Revised School Code contains generally the same requirements concerning meningococcal meningitis. The Department of Education, in cooperation with the Department of Community Health, must develop and make available to school districts, public school academies, and nonpublic schools information that meets these requirements. Under the bill, this also applies to information meeting the requirements concerning HPV.

MCL 333.9205b (S.B. 415)

MCL 380.1177a (S.B. 416)

BACKGROUND

According to the Centers for Disease Control and Prevention, "HPV is a common virus that is passed on through sexual contact. Most of the time HPV has no symptoms so people do not know they have it. There are many different strains or types of HPV. Some types can cause cervical cancer in women and can also cause other kinds of cancer in both men and women. Other types of HPV can cause warts in the genital areas of men and women...

HPV is the most common sexually transmitted infection in the United States, with about 20 million people currently infected. Women have an 80 percent chance of getting HPV by the time they are 50. Every year in the U.S., about 6.2 million people get a new HPV infection. HPV is most common in young people who are in their late teens and early 20s..."

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

The American Cancer Society estimates that, in 2008, about 11,070 cases of invasive cervical cancer will be diagnosed, and about 3,870 women will die from cervical cancer in the United States. According to the DCH, 101 women in Michigan died from the disease in 2006. The Department also reports that the most important risk factor for cervical cancer is infection with HPV. Recently, the CDC released the results of a study showing that one in four female adolescents is infected with at least one sexually transmitted infection, and the most common one is cancer- and genital wart-associated HPV. These statistics underscore the need for families to be informed about the virus and the availability of the HPV vaccine.

Although there are no available data regarding the number of girls being vaccinated against HPV, it is possible that they and their parents 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. Clinical studies of Gardasil showed minimal adverse effects, but 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, and they might not be aware that State and Federal health programs will cover the HPV vaccine for some uninsured or underinsured children and teens.

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 infection. The bills require materials about HPV and the vaccine to be posted on the DCH website, require the Department to encourage schools to provide the information to parents, and require schools to include this information if they provide other health-related information to parents of 6th-, 9th-, and 12th-graders. These measures respect the authority of parents to make decisions about their children's health, while helping to ensure that those decisions are made knowledgeably.

Supporting Argument

House Bill 5322 is 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. House Bill 5322 takes the same approach for HPV.

Legislative Analyst: Suzanne Lowe

FISCAL IMPACT

Senate Bill 415

The bill will 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.

House Bill 5322

The bill will have no fiscal impact on State government.

Local school districts will see minimal, if any, increases in costs associated with disseminating additional health information as required by this legislation.

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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.