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BILL ANALYSIS



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Senate Bill 1416 (Substitute S-1 as passed by the Senate)
Senate Bill 1417 (as passed by the Senate)
Sponsor: Senator Bev Hammerstrom
Committee: Health Policy

Date Completed: 10-5-06

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 genital 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 Prevention (CDC), the vaccine, which is called Gardasil, is 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 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 FDA's approval of the vaccine, many people believe that State law should require 6th-grade girls to be vaccinated, unless their parents or guardians object.

CONTENT

Senate Bill 1416 (S-1) would amend the Public Health Code to do the following:

- Create the Childhood Immunization Advisory Committee in the Department of Community Health (DCH).
- Require the Committee to assist the DCH in identifying materials containing information about HPV and cervical cancer risks, and other diseases for which the DCH could recommend immunization.

- Require the Committee to review and approve materials or recommendations identified by the DCH.
- Require legislative approval of the materials or recommendations approved by the Committee.
- Require the DCH to inform schools of the availability of materials approved by the Legislature.
- Require the parent, guardian, or person in loco parentis 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 a health care provider administering the HPV vaccine to provide a statement or certificate, or make an entry on a certificate.
- Require a health care provider, before immunizing a child, to give the parent, guardian, or person in loco parentis the most recent vaccine information statement and obtain the consent of the parent, guardian, or person in loco parentis.

Senate Bill 1417 would amend the Revised School Code to 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.

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

Senate Bill 1416 (S-1)

Advisory Committee; Recommendations

The bill would create the Childhood Immunization Advisory Committee within the DCH. The Committee would have to consist of two individuals appointed by the Senate Majority Leader, two appointed by the Speaker of the House of Representatives, and three individuals appointed by the Governor. The Committee would have to meet as it determined necessary to carry out the duties prescribed by the bill.

The Committee would be required to assist the DCH in identifying materials containing information regarding the risks associated with HPV and cervical cancer and any other diseases for which the DCH could recommend immunization or immunization information, and the availability, effectiveness, and potential risks of the HPV vaccine and the vaccinations to protect against those diseases. The Committee would have to approve the proposed materials or recommendations identified by the DCH, and oversee the marketing and dissemination of the approved information.

In addition, the Committee would be required to review and approve recommendations made by the DCH to revise the list of childhood immunizations to be administered, to include additional vaccinations that had been approved by the Food and Drug Administration.

Once the informational materials had been identified and approved or the recommendations for additional childhood vaccinations had been approved, the Committee would have to forward for approval a copy of the materials or recommendations to the standing committees in the Senate and the House that consider issues pertaining to public health. Within 45 days after the materials or recommendations were forwarded and received, the Legislature would have to approve or reject the recommendations by concurrent resolution adopted by both standing committees of the Senate and the House that consider public health issues and adopted by both houses of the Legislature by recorded vote. If the proposed materials or recommendations were not submitted on a legislative session day, the 45 days would

begin on the first session day after the recommendations were submitted. The 45 days would have to include at least nine legislative session days.

Legislative disapproval would have to be expressed by concurrent resolution adopted by each house of the Legislature. The concurrent resolution would have to state specific objections to the proposed materials or recommendations. If they were not rejected within the 45-day period, the recommendations would be approved. ("Legislative session day" would mean each day in which a quorum of either the House or the Senate, following a call to order, officially convenes in Lansing to conduct legislative business.)

Once the informational materials had been approved as described above, the DCH promptly would have to notify each school in the State of the availability of the materials and make them available on its website.

Health Care Providers

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 written statement or a certificate of that immunization).

The Code requires the health care provider to report to the DCH each immunization administered by the provider, unless the parent, guardian, or person in loco parentis of the child objects. Before administering an immunizing agent to a child, a health care provider must notify the parent, guardian, or person in loco parentis of the right to object to the reporting. The bill also would require the health care provider, before immunizing a child, to do the following:

- Give the parent, guardian, or person in loco parentis the most recent vaccine information statement as required for all other childhood immunizations.
- Obtain the consent of the parent, guardian, or person in loco parentis to administer the immunizing agent as

required for all other childhood immunizations.

Immunization of 6th Graders

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

- A statement or certificate of immunization 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.

Rules

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

Human Papillomavirus; HPV Vaccine

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."

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."

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 6th-grade 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 11- and 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 and (after they were approved by the proposed Committee) notify schools of the availability of the materials, and post them on the DCH 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.

Response: Under the administrative rules, a requirement for immunization with a specific vaccine may be suspended temporarily at the request of the DCH Director due to inadequate supply. The bills also should allow an exception in the event of a shortage of the HPV vaccine.

Supporting Argument

Under current law, the DCH may decide to require new childhood immunizations simply by going through the administrative rules process. Senate Bill 1416 (S-1) would give the Legislature an active role in this decision-making, by creating the Childhood Immunization Advisory Committee, requiring the DCH to make recommendations to the Committee, requiring the Committee to approve them, and then requiring the Legislature to approve or reject the recommendations. The addition of a new vaccination requirement, such as the one for HPV, can raise serious public policy questions, and elected officials should have input into the message that is sent to the public.

Response: The Michigan Advisory Committee on Immunization already exists. This Committee was formed in 1992 to advise the DCH on immunization-related diseases. Current membership includes 20 representatives from the Michigan Health and Hospital Association, the Michigan State Medical Society, the Michigan Osteopathic Association, the Michigan Chapter of the American Academy of Family Physicians, and various other public health and health-related organizations. The Committee meets quarterly and provides the DCH Division of Immunization with guidance on State policy recommendations.

Furthermore, the Legislature has a role in the rule-making process because all rules must be submitted to the Joint Committee on Administrative Rules (JCAR), which must notify the appropriate standing committees. If JCAR objects to a rule (on one of the grounds specified in statute), the Legislature can pass a bill to rescind the rule on its effective date, delay the effective date of the rule, or repeal the statutory provision under which the rule was authorized.

Opposing Argument

Despite the provisions allowing parents and guardians 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, or could undermine the consideration of abstinence as a way to prevent sexually transmitted diseases. 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.

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. Furthermore, the State already requires vaccinations for hepatitis B, which is transmitted through sexual activity or needle-sharing.

Opposing Argument

According to the CDC, the retail cost of the HPV vaccine is \$120 per dose (\$360 for the full series). This expense would be an imposition on families who do not have health insurance or whose insurance does not cover the HPV vaccine. Although the CDC reports that Federal health programs such as Vaccines for Children (VFC) will cover the HPV vaccine for children and teens who are uninsured, Medicaid-eligible, American Indian, or Alaska Native, that coverage is available only if Federal funds are appropriated.

Response: The price of the vaccine could be far less than the cost of future medical treatment, especially for a serious condition such as cancer.

Opposing Argument

The long-term effects of the vaccine should be investigated before it is mandated. According to the FDA, the manufacturer of Gardasil has agreed to conduct additional studies to evaluate the vaccine's general safety and effectiveness.

Legislative Analyst: Suzanne Lowe

FISCAL IMPACT

Senate Bill 1416 (S-1)

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 providing support to the Childhood Immunization Advisory

Committee, providing information to each school in the State, and modifying the Department's website 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
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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.