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FISCAL IMPACT STATEMENT

LS 7012

BILL NUMBER: SB 327

NOTE PREPARED: Feb 12, 2007

BILL AMENDED: Feb 8, 2007

SUBJECT: Immunization for School-Age Girls.

FIRST AUTHOR: Sen. Lawson C

FIRST SPONSOR: Rep. Mays

BILL STATUS: As Passed Senate

FUNDS AFFECTED: **GENERAL**
 DEDICATED
 FEDERAL

IMPACT: State & Local

Summary of Legislation: This bill requires a school to: (1) provide information to each parent of a female child entering Grade 6 concerning the link between cervical cancer and the human papillomavirus (HPV) infection and of the availability of an immunization; (2) collect written statements from the parent indicating whether the child received the immunization; and (3) file a written report with the State Department of Health (ISDH) stating the number of required female students who have received the immunization and the number of female students who have not received the immunization.

The bill requires the Department to provide a school with the information on cervical cancer and HPV and prescribe the format for the written statement.

Effective Date: July 1, 2007.

Explanation of State Expenditures: *Summary:* The state fiscal impact of advising parents of the availability of HPV immunization will depend on the number of girls entering Grade 6 in Indiana who would subsequently present to local health departments for the immunization and on the availability of the vaccine at the local health departments. The bill does not require the children be immunized. The cost to cover all girls entering Grade 6 who are projected to seek immunizations from local health departments is believed to be approximately \$2.67 M for HPV vaccine only.

Reporting Requirements: Local school corporations are required to distribute information regarding the availability of the HPV vaccine to parents of girls entering the 6th grade. The school is to collect signed statements from parents regarding the immunization status of the girls or whether the parent has decided not to have the child immunized. The reported information is to be compiled by the school and reported to the

State Department of Health. The bill requires the ISDH to develop the information regarding the HPV vaccine that is distributed to the parents and the format for the report required to be signed by the parent and returned to the school. Both requirements should be accomplished within the current level of resources available to the Department and to school corporations.

Local Health Departments/Federal 317 Funds: Local health departments administer immunizations to approximately 21% of the state's children. This population consists of uninsured or underinsured children who are referred to local health departments by schools and doctors. The ISDH has reported that supplying HPV immunizations could have a state fiscal impact for this group due to the price of the vaccine and the number of doses required. Vaccines necessary for other state-required immunizations administered by the local health departments have been purchased with federal "317 Program" funds in the past. However, federal funding for the 317 Program has been limited for several years, and the Department reports there are insufficient grant funds available to buy additional vaccines. The HPV vaccine costs the State Department of Health \$96.00 per dose under contracts negotiated by the Centers for Disease Control and Prevention (CDC).

There are approximately 44,100 12-year-old girls in the state, of which 21% are estimated to present to the local health department clinics for immunization services. This results in an estimated 9,261 girls that may request 3 doses of HPV vaccine to be fully immunized. This could result in a total cost of \$2.67 M for vaccine. This money would provide for only those girls who may request the vaccine due to being made aware of the availability of the immunization; it would not include older girls requesting to receive HPV immunizations from county health departments.

The Department has also estimated a cost of \$40 for the administration of 3 doses of the vaccine resulting in an additional cost of \$370,000 if all families of girls entering 6th grade request immunizations. Local health departments may or may not charge an administration fee for immunization services. The state has not provided financial assistance in the past to the local health departments for the administration of additional or new vaccines, such as varicella. HPV vaccine can be given at the same time as some of the other vaccines recommended or required for this age group. The impact this bill would have on the necessary local resources to administer additional doses of vaccine is not known.

Medicaid: Girls eligible for Medicaid are entitled to the HPV vaccine through the federal Vaccines for Children program (VFC) by virtue of the Advisory Committee on Immunization Practices (ACIP) recommendation for the VFC program. Immunizations covered under the Early and Periodic Screening, Diagnostic, and Treatment benefit (EPSDT) follow the ACIP recommended schedule. There is no cost to Medicaid for the vaccine itself. The cost of the administration of the vaccine for Medicaid-eligible children is a required cost under the EPSDT program. Adding the requirement of HPV immunization for girls entering the sixth grade has no impact on Medicaid costs.

Children's Health Insurance Program (CHIP): The Department of Health also purchases vaccines for children covered by Package C of Hoosier Healthwise (CHIP). These children are considered to have health insurance and therefore are not covered by the VFC entitlement. It is less costly for the Department to purchase the vaccines used for CHIP children than it would cost to buy the products on the open market. This mechanism also makes the provision of immunization services within the Hoosier Healthwise program appear seamless to patients and providers. CHIP children's vaccines are purchased at the lowest price available to the state, and the state pays approximately 26% of the total cost. If providers are following the ACIP schedule of recommended childhood immunizations, this bill should have no impact on the CHIP program.

Federal Vaccines For Children Program (VFC): Another segment of the population is eligible for the federally funded Vaccines for Children (VFC) program or is privately insured. The VFC entitlement program provides federally purchased vaccines for children from birth to age 18 who are enrolled in Medicaid, uninsured, or who are Native Americans. Children who have insurance that does not cover immunizations may receive VFC benefits at Federally Qualified Health Care Centers or Rural Health Clinics. Private providers may also enroll in the VFC Program and administer vaccines to eligible children.

State Employees Health Benefits: State employee health benefits cover immunizations. The status of the coverage for HPV vaccine is not known at this time. [This information will be updated when the information becomes available.]

Funding information: CHIP is jointly funded by the state and federal governments. The state share of program expenditures is approximately 26%. CHIP medical services are matched by the federal match rate (FMAP) in Indiana at approximately 74%. Administrative expenditures are generally matched at 50%. Unlike Medicaid, federal CHIP program funding is capped.

Background Information: (Source: ISDH Immunization Program) HPV causes cervical cancer and genital warts. At least 50% of sexually active men and women will have a genital infection with HPV during their lifetime. Most infections are asymptomatic (people do not know they are infected) but can transmit the virus to a sex partner. When infection with "high risk" strains of HPV persists, it results in abnormal Pap tests and is a major risk factor for cervical cancer.

HPV infections are acquired soon after sexual activity begins – in one study of college students, 40% were infected 16 months after onset of sex. Persistent infection with HPV can lead to the development of cervical cancer. Projections for cervical cancer cases in the U.S. in 2006 are 9,700 new cases and 3,700 deaths. It should be noted that HPV and cervical cancer disproportionately affect African American and Hispanic women. The lifetime risk of dying from cervical cancer is twice as high for African American women and 64% higher for Hispanic women than for white women.

The first vaccine to protect against HPV infection – Gardasil – was licensed by the Food and Drug Administration in June 2006. This vaccine protects against infection from the four strains of HPV that cause 70% of cervical cancers and 90% of cases of genital warts. Gardasil is currently licensed for use in females 9-26 years of age. Although studies are being done on the use of this vaccine in males, it is not yet licensed for males. A second HPV vaccine may be licensed in the future to provide protection against two strains of HPV that cause most cervical cancer.

The vaccine is most effective when it is given before the onset of sexual activity and the immune response to the vaccine is strongest at the youngest ages. It is not yet known how long (how many years) protection from the vaccine will last.

The Advisory Committee on Immunization Practices (ACIP) recommends HPV vaccine for:

- Routine vaccination for 11-12 year old girls
- Catch-up vaccination for 13-26 year old females
- Girls age 9-10 years may receive the vaccine at provider discretion

HPV vaccine is administered through a series of three injections over a 6-month period of time (first injection, then others are given 2 and 6 months later). It may be given with other vaccines. The vaccine retail cost is \$120 per dose. The vaccine was tested in more than 20,000 young females (ages 16-26 years) and

appears to have no serious side effects.

Since cervical cancer takes many years to develop, the impact of an effective HPV vaccine on cervical cancer rates may not be apparent for decades. The impact of the vaccine on cervical cancer precursors (abnormal Pap tests results) and genital warts may be realized sooner. The vaccine is not a treatment for women who are already infected with any of the four strains of HPV in the vaccine, but it can prevent infection with strains 6, 11, 16, or 18 not previously acquired.

The vaccine will not replace cervical cancer screening (Pap tests). Even with extensive vaccine coverage, cervical cancer screening must continue because about 30% of cervical cancers are caused by viruses not in the current vaccine.

Explanation of State Revenues:

Explanation of Local Expenditures: Local health department clinics may have three additional immunizations required for administration depending on the availability of the vaccine. The impact this requirement would have on the necessary local resources is unknown.

Local government and schools could see an impact in health insurance costs.

Explanation of Local Revenues:

State Agencies Affected: State Department of Health; Children's Health Insurance Program and Office of Medicaid Policy and Planning, Family and Social Services Administration.

Local Agencies Affected: Local health departments; School corporations; Local governments.

Information Sources: Charlene Graves, M.D., Indiana State Department of Health; National Immunization Program, Vaccines for Children (VFC), Website at: <http://www.cdc.gov/nip/vfc/about.htm>; CHIP, Office of Medicaid Policy and Planning, Family and Social Services Administration.

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