

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Health Regulation Committee

BILL: SB 1116

INTRODUCER: Senator Altman

SUBJECT: Human Papillomavirus

DATE: February 17, 2012

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Davlantes</u>	<u>Stovall</u>	<u>HR</u>	<u>Pre-meeting</u>
2.	_____	_____	<u>ED</u>	_____
3.	_____	_____	<u>BC</u>	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

I. Summary:

This bill requires the Department of Health (DOH) to add the human papillomavirus (HPV) to the list of communicable diseases for which immunizations are recommended. It also requires the DOH to create informational material about the connection between HPV and cervical cancer, the availability of a vaccine to prevent HPV infection, and the recommendation that all girls receive the vaccine before entering eighth grade. The DOH will provide this material to public schools for distribution to the parents and guardians of all rising sixth graders.

The bill creates one undesignated section of law.

II. Present Situation:

CDC and FDA

The Food and Drug Administration (FDA) is a federal agency within the Department of Health and Human Services (HHS) responsible for protecting public health by assuring that foods are safe, sanitary, and properly labeled; human and veterinary drugs, vaccines, and biological products, and medical devices are safe and effective; assuring cosmetics and dietary supplements are safe and properly labeled; regulating tobacco products; and helping the public get the accurate science-based information they need to use medicines, devices, and foods to improve their health.¹ The Center for Biologics Evaluation Research (CBER) within the FDA employs highly trained medical personnel to determine the indications, effectiveness, and side effects of

¹ FDA, *What does FDA do?*, available at: <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194877.htm> (last visited on January 11, 2012).

all vaccines as well as to monitor their manufacturing for quality control.² The CBER approves vaccines for use in certain populations but does not provide recommendations for their administration.

The Centers for Disease Control and Prevention (CDC) is a part of HHS which focuses on public health, both nationally and internationally. The CDC works with partners throughout the nation and the world to monitor health, detect and investigate health problems, conduct research to enhance prevention, develop and advocate sound public health policies, implement prevention strategies, promote healthy behaviors, and foster safe and healthful environments.³ The Advisory Committee on Immunization Practices (ACIP) within the CDC develops written recommendations for the administration of vaccines, including the appropriate timing, dosage, and contraindications. The ACIP is the only entity in the federal government which makes such recommendations.⁴

Human Papillomavirus and Vaccines

HPV is a virus which infects the skin and mucous membranes. More than 100 types of HPV have been discovered. The virus is transmitted by skin-to-skin contact during sexual activity and is so prevalent that almost everyone is infected by one or various strains. HPV infection is usually asymptomatic, although certain types cause diseases such as genital warts and cervical cancer.

Vaccines currently exist for HPV types 6, 11, 16, and 18. HPV types 6 and 11 cause benign warts to grow around the genitals, in the respiratory tract, in the eye, or on whatever body part is exposed to infection during sexual activity; however, these strains can also lead to lung or vulvar cancer. HPV types 16 and 18 cause more malignant diseases such as cancer of the lung, respiratory tract, sinuses, eye, mouth, esophagus, anus, vulva, cervix, and penis.⁵ The most common cancer caused by HPV types 16 and 18 is cervical cancer, which affects more than 12,000 women per year. Oropharyngeal (mouth and throat) cancers are the most common cancers caused by HPV in men.⁶

The FDA has approved two vaccines against HPV. The first, Gardasil, protects against HPV types 6, 11, 16, and 18 and is recommended for all people aged 9 to 26.⁷ The second, Cervarix, protects against types 16 and 18 and is recommended for women aged 9 to 25.⁸ Both vaccines are given as three shots over six months and are most effective when administered before the onset of sexual activity.⁹

² FDA, *How does FDA assess the safety of vaccines?*, available at:

<http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194586.htm> (last visited on January 11, 2012).

³ CDC, *CDC Mission*, available at: <http://www.cdc.gov/about/organization/mission.htm> (last visited on January 11, 2012).

⁴ CDC, *About ACIP*, available at: <http://www.cdc.gov/vaccines/recs/acip/default.htm> (last visited on January 11, 2012).

⁵ Medscape Reference, *Human Papillomavirus*, available at: <http://emedicine.medscape.com/article/219110-overview> (last visited on January 11, 2012).

⁶ CDC, *HPV Vaccine- Questions & Answers*, available at: <http://www.cdc.gov/vaccines/vpd-vac/hpv/vac-faqs.htm> (last visited on January 11, 2012).

⁷ FDA, *Gardasil*, available at: <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM094042> (last visited on January 11, 2012).

⁸ FDA, *Cervarix*, available at: <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm186957.htm> (last visited on January 11, 2012).

⁹ CDC, *HPV Vaccines*, available at: <http://www.cdc.gov/hpv/vaccine.html> (last visited on January 11, 2012).

The CDC recommends that all children be vaccinated against HPV at age 11 or 12.¹⁰

Vaccines Currently Required by Rule or Statute

Certain vaccines are required before any person can be educated in the state, either in public, private, or virtual schools, unless that person is given a religious or medical exemption.¹¹ Immunization requirements vary by the grade of the student. There are currently no *recommended* vaccines mentioned in statute or rule.

Before entering pre-kindergarten, a child must be vaccinated against diphtheria, tetanus, pertussis, polio, measles, mumps, rubella, hepatitis B, chicken pox, and *Haemophilus influenzae* type b. Before entering kindergarten, a child must have received at least four doses of the diphtheria, tetanus, and pertussis vaccine; at least three doses of the polio vaccine; two doses of the measles, mumps, and rubella vaccine; at least two doses of the hepatitis B vaccine; and one or two doses of the chicken pox vaccine, depending on the age of the child. Additionally, one dose of the tetanus-diphtheria-pertussis vaccine is required before a student may begin seventh grade.¹²

III. Effect of Proposed Changes:

Section 1 requires the DOH to adopt a rule adding HPV to the list of communicable diseases for which immunizations are recommended. It also requires that, beginning with the 2012-2013 school year, each school must provide the parent or guardian of any rising sixth grade student with information regarding the connection between HPV and cervical cancer, the availability of a vaccine to prevent HPV infection, and the recommendation that all females receive this vaccine before entering eighth grade. Such information will be provided to schools by the DOH.

Section 2 provides that the bill will take effect upon becoming a law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

¹⁰ *Supra* fn. 6.

¹¹ Section 1003.22, F.S., and Rule 64D-3.046, F.A.C.

¹² DOH, *Immunization Guidelines*, available at http://www.doh.state.fl.us/disease_ctrl/immune/schoolguide.pdf (last visited on January 11, 2012).

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Public school students and their parents and guardians will be better educated about HPV, its effects, and available vaccines.

C. Government Sector Impact:

The DOH will experience negligible fiscal impact.¹³

VI. Technical Deficiencies:

Lines 20-23 are grammatically incorrect. "Provide the parent or guardian . . . information" should instead be "provide the parent or guardian . . . *with* information."

VII. Related Issues:

Section 1(1) of the bill requires that the DOH add HPV to the list of communicable disease for which immunizations are recommended. However, the DOH does not keep a list of recommended immunizations, nor does it have authority to do so. Rather, it maintains a list of *required* immunizations which are provided in statute and rule.

Section 1(2) of the bill requires that the parents or guardians of rising sixth grade public school students receive information concerning HPV and available vaccines. It is unclear why the parents and guardians of private school students will not receive the same information, as HPV may also affect their children, and the DOH maintains the same immunization requirements for both public and private school students.

Furthermore, the provisions for HPV education materials in Section 1(2) do not offer a full picture of diseases caused by the virus or vaccine recommendations. While cervical cancer is the most common malignant disease caused by HPV, HPV infection can also lead to genital warts, lung cancer, anal cancer, and several other tumors. Also, the FDA has approved an HPV vaccine for both men and women from ages 9-26, and the CDC recommends that the vaccine be administered by ages 11-12 (generally the age of a sixth grade student). Neither the FDA nor the CDC makes any statement that the vaccine should be administered to females before entering eighth grade.

¹³ Department of Health, *2012 Bill Analysis, Economic Statement, and Fiscal Note for SB 1116*. A copy is on file with the Senate Health Regulation Committee.

The bill references the FDA to determine which children should receive information on HPV vaccination. Although the FDA approves vaccines for disease prevention in certain populations, the CDC is tasked with developing recommendations for the optimum administration of these vaccines. Thus, the CDC may be a more appropriate entity to reference in lines 21-22 than the FDA.

Finally, the bill states the DOH will disseminate information regarding HPV to schools. However, information from state agencies for parents or guardians is usually provided to school districts by the Department of Education.

VIII. Additional Information:

- A. **Committee Substitute – Statement of Substantial Changes:**
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

- B. **Amendments:**

None.