The Florida Senate

PROFESSIONAL STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

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

Prepared By: Education Pre-K - 12 Committee					
BILL:	CS/SB 660				
INTRODUCER:	Education Pre-K-12 Committee and Senators Fasano, King, and Deutch				
SUBJECT:	Human Papillomavirus (HPV)/Schools				
DATE:	April 11, 2007 REVISED:			_	
ANALYST		STAFF DIRECTOR	REFERENCE		ACTION
1. Harkey		atthews	ED	Fav/CS	
2.			HP		
3.			EA		
4.		_			
5.		_			
5.					

I. Summary:

This bill requires public and private schools in the state to provide specified information to the parent or guardian of each student entering sixth grade for whom the human papillomavirus (HPV) vaccine is approved by the United States Food and Drug Administration. The required information concerning the connection between HPV and cervical cancer and the HPV vaccine must be prescribed by the Department of Health and must be presented to parents or guardians beginning with the 2008-2009 school year.

This bill creates one unnumbered section of the Florida Statutes.

II. Present Situation:

Cervical Cancer

Cancer of the cervix is the second most common type of cancer among women worldwide. About 80 percent of cervical cancer cases occur in developing countries. In 2005, the American Cancer Society estimated that approximately 490,000 new cases would be diagnosed worldwide that year. In the United States, cervical cancer is the 14th most common type of cancer in women. An estimated 11,150 cases of invasive cervical cancer are expected to be diagnosed in the United States in 2007. Of those, 850 cases of new cervical cancer are estimated to occur in Florida in 2007. Cervical Cancer incidence rates have decreased approximately 75 percent and

³ American Cancer Society. *Cancer Facts and Figures* 2007. p. 20.

¹ American Cancer Society. Cancer Facts and Figures 2005. p.27

 $^{^{2}}$ Ibid.

death rates have decreased approximately 70 percent since the 1950s, largely because of screening with the Papanicolaou (Pap) test.⁴ Cervical cancer is one of the most successfully treated cancers with a 5-year survival rate of 92 percent for localized cancers.⁵

In the United States cervical cancer incidence and mortality differ by racial/ethnic group and geographical area. The incidence for black women is 1.5 times higher than that for white women, and the death rates for black women are twice that for white women. Incidence for Hispanic women is higher than for white women. Incidence and mortality rates are higher in the Southern states and Appalachia. Cervical cancer is diagnosed at an early stage more often in white women (53 percent) than in African American women (45 percent) and in women younger than age 50 (63 percent) than in women 50 and older (38 percent).

Human Papillomavirus (HPV)

Genital human papillomavirus is the most common sexually transmitted infection in the United States. An estimated 6.2 million persons are newly infected every year. The majority of infections are transient and asymptomatic with 70 percent of new infections clearing within one year and 90 percent clearing within 2 years. The median duration of a new infection is 8 months. However, persistent HPV infection with high-risk types of HPV is the most important risk factor for cervical cancer precursors and invasive cervical cancer. Of approximately 100 HPV types, over 40 types affect the genital area. Approximately 70 percent of cervical cancers worldwide are caused by HPV types 16 and 18. While infection with high-risk types of HPV is considered necessary for the development of cervical cancer, the majority of women with high-risk HPV infection do not develop cancer.

The Licensed HPV Vaccine

The U.S. Food and Drug Administration licensed a quadrivalent HPV vaccine on June 8, 2006, which has been shown in clinical trials to have high efficacy in preventing persistent HPV infection, cervical cancer precursor lesions, vaginal and vulvar cancer precursor lesions and genital warts caused by HPV types 6, 11, 16, and 18 among females who had not already been infected with the respective HPV type. The vaccine is administered by an intramuscular injection in three doses administered over a 6-month period. The recommended age for vaccination of females is 11-12 years. The vaccine can be administered to females as young as age 9 and as old as age 26. The vaccine is produced by Merck and Co., Inc., and is marketed under the name GARDISILTM.

⁴ Centers for Disease Control and Prevention. "Quadrivalent Human Pailllomavirus Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP)". Morbidity and Mortality Weekly Report. Vol. 56 (Early Release). March 12, 2007.

⁵ American Cancer Society. Cancer Facts and Figures 2007. p. 21

⁶ Ibid.

⁷ Ibid.

⁸ Centers for Disease Control and Prevention. "Quadrivalent Human Pailllomavirus Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP)". Morbidity and Mortality Weekly Report. Vol. 56 (Early Release). March 12, 2007.

⁹ Ibid.

 $^{^{10}}$ Ibid.

¹¹ Ibid.

School Immunizations

Section 1003.22(4), F.S., requires immunizations for poliomyelitis, diphtheria, rubeola, rubella, pertussis, mumps, tetanus, and other communicable diseases as determined by rules of the Department of Health, as a condition for entry into school. The statute provides two reasons for exemption from this requirement: If the parent objects in writing stating that the immunizations conflict with his or her religious beliefs or if a licensed physician certifies in writing that the child should be exempt from the required immunization for medical reasons.

III. Effect of Proposed Changes:

Beginning with the 2008-2009 school year, each Florida public or private school must provide to the parent or guardian of each student entering sixth grade for whom the human papillomavirus (HPV) vaccine is approved by the United States Food and Drug Administration, information concerning:

- The connection between the HPV and cervical cancer;
- The availability of a vaccine that helps prevent HPV infection; and
- The recommendation that the vaccine be given to females before they enter sixth grade.

The Department of Health must prescribe the required information to be provided to parents or guardians.

There is not an HPV vaccine licensed for males.

The bill will take effect July 1, 2007.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Any private school that enrolls sixth grade students for whom the HPV vaccine is approved by the United States Food and Drug Administration might incur a slight cost for distributing the information prescribed by the Department of Health.

C. Government Sector Impact:

DOH would incur the cost of prescribing the information that each public and private school would be required to provide to parents and guardians concerning the connection between HPV and cervical cancer and the HPV vaccine.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

This Senate Professional Staff Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

VIII. Summary of Amendments:

None.

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