

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide Limited Government, Safeguard Individual Liberty, Empower Families: The bill requires that as of the 2008-2009 school year, a student who is 11 or 12 years of age may not be admitted to any private or public school in this state until that student submits to the school acceptable evidence of vaccination for the human papillomavirus (HPV) or proof that, after receiving information concerning HPV and cervical cancer and the availability of a vaccine preventing HPV, the parent or guardian has elected that the student not receive the vaccine.

Requires the Department of Education (DOE), in consultation with the Department of Health (DOH), to determine the content of the information the parent is to receive.

B. EFFECT OF PROPOSED CHANGES:

Current Law

Section 1003.22(3), F.S., requires students to receive seven named immunizations: poliomyelitis, diphtheria, rubeola, rubella, pertussis, mumps, tetanus; and, allows the Department of Health to supplement the list with immunizations for other communicable diseases, as adopted in rule. The DOH, in consultation with the DOE, has adopted rules governing the immunization of children against, the testing for, and the control of preventable communicable diseases. The rules include procedures for exempting a child from immunization requirements.

The Department of Health supervises and secures the enforcement of the required immunizations. *Immunizations required by s. 1003.22(3), F.S., must be made available at no cost from the county health departments.*

Neither s. 1003.22(3), F.S., or the agency rules, require immunization for HPV. However, the DOH "routinely informs the parents or guardians of female patients in the age range of 11-12 years of age who present for services at county health department that the HPV vaccine is available [at no cost] for those who are eligible under the federal Vaccines for Children Program (VFC). Children age 0-18 are eligible for the VPC Program if they meet one of the following criteria: Medicaid covered, uninsured, underinsured (insurance does not cover immunization), Alaskan Native or American Indian."¹

Proposed Changes

"HPV is the most common sexually transmitted virus in the United States. By age 50, at least 80% of women will have acquired the HPV infection at some point in their lives of at least one or more of the 30 known strains of HPV that infect the genital tract. The HPV vaccine was released in June by the FDA **for use in girls** age 9-26. The Advisory Committee on Immunization Practices, a panel of expert advisors to the Centers for Disease Control, recommended the vaccine for 11 to 12 year old girls. Gardasil (Merek & Co., Inc.) **protects against 4 strains of HPV.**"²

The bill requires that beginning with the 2008-2009 school year and extending to each subsequent school year thereafter, each public and private school in Florida will be required "to provide each 11 or 12 year old student, and the parent or guardian, information regarding the connection between [HPV] and cervical cancer, as well as the availability of a vaccine to prevent HPV", a sexually transmitted

¹ DOH analysis, HB 561, Feb. 13, 2007

² HB 561 Vaccination for Cervical Cancer by Rep. Ed Homan, MD, March 2007.

disease (STD). However, as indicated in the above-quoted material, the vaccine does not totally “prevent HPV”; the vaccine protects against 4 of the most common 30 strains of the virus.

The bill further requires that beginning with the 2008-2009 school year and extending to each subsequent school year thereafter, *students* who are 11 or 12 years of age are excluded from admission to any school in the state, public or private, until *each student* provides evidence of vaccination for HPV, or proof that the parent or guardian has elected for the student not to receive HPV vaccine after receiving the HPV information required to be given to the student and parent by the school.

The HPV vaccine on the market, at this time, is gender specific and is licensed for *females only*. Nonetheless, the bill requires boys to receive the vaccine as well.

The bill requires a principal or other person in charge of a public and private school to prohibit the admission of students to school who are 11 or 12 years of age until the student provides evidence of vaccination for the HPV series, or proof that the parent or guardian has elected for the student to not receive HPV vaccine after receiving the HPV information required to be provided by the school. This requires each public and private school with students that are 11 or 12 years of age to develop policy and procedures to implement the provisions of this proposal.

Since the HPV vaccine is given in a series of three injections over a 6-month period, schools (public and private) and district school boards will need to develop and implement an ongoing immunization tracking system to monitor students’ completion of the three dose series over a six-month timeframe.

Finally, the bill requires that the DOE, in consultation with the DOH, prescribe the content of the HPV information requirement to students who are 11 or 12 years of age and their parents or guardians.

This bill takes effect July 1, 2008.

C. SECTION DIRECTORY:

Section 1. Creates an unnumbered section regarding required information and immunization for HPV.

Section 2. Provides effective date of July 1, 2008.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

This bill does not appear to have a fiscal impact on state government revenues.

2. Expenditures:

DOH has provided a fiscal analysis, which is based on the cost of the vaccine as well as the additional staffing needed to provide the services at the county health departments.

DOH construed the bill literally to mean that whether a student is 11 or 12 years old, the student is to receive the vaccine: “provide to each **student** who is 11 years of age **or** 12 years of age.” However, DOH did not include boys in its calculations, despite the fact that a literal interpretation of the bill includes boys. DOH did not include boys because the vaccine is not approved for boys, at this time. Irrespective of what may have been intended by a bill, an analysis of a bill must address the provisions of the bill. Accordingly, a literal interpretation of the bill would increase the fiscal impact over the DOH projections for the cost of the vaccine.

Currently, according to DOH, there are approximately 257,563 girls that are 11 or 12 years old. The Vaccines for Children (VFC) program, a federally funded program, will cover the cost of vaccinating approximately 116,660 of these girls³. The remaining 140,903 females will be eligible to be vaccinated at the county health departments, free of charge. Some of these girls will be vaccinated in private health care clinics and thus covered by private health care insurance. However, DOH estimates, from experience, that approximately 30% of girls who normally receive services in the private health care sector will be referred to county health departments for service. Thus, approximately 42,271 girls will need to be served by the county health departments.

DOH will have to purchase 126,813 doses of the HPV vaccine (42,271 x 3 injections) at \$96 per dose for a total of \$12,174,048 – girls only.

In addition, more staff would be needed to administer the additional service in the 67 county health departments. DOH projects the need for 100 additional nurses; and, including overhead, the cost would be approximately \$3.8 million (without factoring in annualization or recurring costs). Without administrative overhead, and with a more conservative assessment of staff needed, the cost would be closer to approximately \$1.5 million. However, these estimates only relate to the provision of the vaccines to girls, not boys. Including boys, would substantially increase the cost.

A strike all amendment has been filed by the sponsor, which provides, among other things that “beginning with the 2011-2012 school year, each student for whom the human papillomavirus vaccine is approved by the United States Food and Drug Administration” must either be immunized or elect not to receive the vaccine. Accordingly, one might conclude from the continued inclusion of boys (i.e., students), that by 2011-2012 a vaccine could be available for use on boys. Therefore, a fiscal analysis including that population of recipients would not be inappropriate.

The DOH and DOE will experience some fiscal impact, though limited, with regard to prescribing the content of the information regarding HPV that the school districts must provide to the students and parents.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

This bill does not appear to have a fiscal impact on local government revenues.

2. Expenditures:

This bill does not appear to be a fiscal impact on local government expenditures.

³ Children age 0-18 are eligible for the VFC program if they meet one of the following criteria: Medicaid covered, uninsured, underinsured (insurance does not cover immunization), Alaskan Native or American Indian.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The private health care sector will assume some burden for the costs of implementing the required vaccinations through administration of additional required vaccinations and the provision of information dissemination and documentation of any exemptions for school attendance. Private health care insurers will also bear the costs of covering the vaccine.

1. Private Sector Costs: Private health insurers who cover the vaccination will be affected by the costs of implementing the bill.
2. Private Sector Benefits: The primary benefits of the bill include potentially lowering the number of cases of cervical cancer due to the increase in HPV vaccinations administered in 11 or 12 year olds.⁴

D. FISCAL COMMENTS:

Public and private schools must disseminate information “to each student who is 11 years of age or 12 years of age and to the parents or guardian regarding the connection between the HPV and cervical cancer and the availability of a vaccine preventing HPV.” (Please note discussion above: the vaccine does not prevent all strains of HPV.) The cost of production and dissemination of such information is indeterminate.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not appear to apply to counties or municipalities.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

This bill does not create rule-making authority.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

D. STATEMENT OF THE SPONSOR

The discovery of a vaccine to prevent the HPV infection that causes most cases of cervical cancer is one of the greatest advances in women's health in the last century.

When the vaccine to prevent Hepatitis B became available it was incorporated into the schools immunization program without hesitation or controversy, despite the fact that Hepatitis B is a sexually transmitted disease just like the HPV virus. The difference being that the Hepatitis B virus is uncommon, but 44% of women and 59% of men in the 20-24 year age group harbor the HPV virus. We need to get this problem under control and we have a vaccine to do it. The fiscal impact in the analysis is overstated because it was done on the original bill that has been rewritten in the strike all

⁴ DOE analysis, HB 561, Feb. 13, 2007
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amendment. This bill is a true representative of IDEA # 88, i.e. better health care through prevention. An up front investment to prevent disease saves many more dollars than treating the disease, in addition to saving lives as well.

IV. AMENDMENTS/COUNCIL SUBSTITUTE CHANGES