HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 127 CS Immunizations
SPONSOR(S): Hays
TIED BILLS: **IDEN./SIM. BILLS:** SB 1160

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Elder & Long-Term Care Committee	7 Y, 0 N, w/CS	DePalma	Walsh
2) PreK-12 Committee	10 Y, 0 N	Beagle	Mizereck
3) Health Care Appropriations Committee	11 Y, 0 N	Money	Massengale
4) Health & Families Council		DePalma	Moore
5)			

SUMMARY ANALYSIS

House Bill 127 CS requires district school boards and private school governing authorities to provide every student's parent specified information about meningococcal disease in accordance with the recommendations of the Department of Health (DOH). The bill requires DOH to adopt rules specifying the age or grade level of students to receive the information, consistent with recommendations of the Centers for Disease Control (CDC). It further requires DOH to make information about the disease available to district school boards and private school governing authorities, who shall determine the means and methods for providing this information to students' parents.

There appears to be no fiscal impact on state or local government. School districts and private school governing authorities may incur minor costs related to the provision of information about meningococcal disease to student's parents.

There is a potential cost to parents or private health insurance companies to cover the costs of the vaccine and administration of the vaccine for those parents who choose to vaccinate their children. According to DOH, the market price of the vaccine is $75–$100 per dose.

The effective date of this bill is July 1, 2006.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide limited government – House Bill 127 CS requires DOH to adopt rules specifying the age or grade level of students to receive information about meningococcal disease consistent with recommendations of the CDC. It requires DOH to make information about the disease available to district school boards and private school governing authorities, who shall determine the means and methods for providing this information to students' parents.

B. EFFECT OF PROPOSED CHANGES:

Meningococcal Disease and Immunization

The *meningococcus* bacterium can cause a life-threatening infection of the bloodstream, meningitis (infection of the brain and spinal cord coverings), or both. Sometimes referred to as spinal meningitis, bacterial meningitis can be quite severe and may result in brain damage, hearing loss, or learning disability. Death occurs in 10 to 14 percent of the 1,400-2,800 cases of meningococcal meningitis that are reported in the U.S. each year.[1] The largest incidence of the disease is in children under age 5, with a second peak in children and young adults between the ages of 15 and 24.[2]

Before the 1990s, *Haemophilus influenzae* type b (Hib) was the leading cause of bacterial meningitis. New vaccines being given to all children as part of their routine immunizations, however, have reduced the occurrence of invasive disease because of *H. influenzae*.[3]

There are five subtypes (or serogroups) of the bacterium that cause meningococcal meningitis (Serogroups A, B, C, Y, and W-135). Two vaccines are available to immunize against Serogroups A, C, Y and W-135: Menomune, licensed in 1981, and Menactra (manufactured by Sanofi Pasteur, and also known as MCV-4), licensed on January 14, 2005 for use in people 11-55 years of age.[4]

On May 26, 2005, the CDC recommended routine administration of the Menactra vaccine for all children 11-12 years old, previously unvaccinated adolescents at high school entry, and college freshmen living in dormitories

> [t]o help achieve vaccination among those at highest risk for meningococcal disease. As the vaccine supply increases, CDC hopes, within three years, to recommend routine vaccination for all adolescents beginning at 11 years of age.[5]

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[1] Morbidity and Mortality Weekly Report; *Prevention and Control of Meningococcal Disease: Recommendations of the Advisory Committee on Immunization Practices*, May 27, 2005, Department of Health and Human Services Centers for Disease Control and Prevention, available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5407a1.htm.
[2] *Vaccine Information Meningococcal Disease*, updated March 11, 2005, National Network for Immunization Information, available at http://www.immunizationinfo.org/vaccineInfo/vaccine_detail.cfv?id=15.
[3] *Division of Bacterial and Mycotic Disease, Disease Information, Meningococcal Disease*, Department of Health and Human Services Centers for Disease Control and Prevention, available at http://www.cdc.gov/ncidod/dbmd/diseaseinfo/meningococcal_g.htm.
[4] There is no licensed vaccine for Serogroup B in the U.S. *Vaccine Information Meningococcal Disease.*
[5] Press Release: *CDC Recommends Meningococcal Vaccine for Adolescents and College Freshman*, May 26, 2005, Department of Health and Human Services Centers for Disease Control and Prevention, available at http://www.cdc.gov/od/oc/media/pressrel/r050526b.htm.

In September 2005, CDC and the U.S. Food and Drug Administration (FDA) issued an alert[6] after reports made to the Vaccine Adverse Event Reporting System (VAERS) indicated that five adolescents had developed Guillain-Barre Syndrome[7] (GBS) following administration of the Menactra vaccine. By November 2005, six Menactra recipients (all ages 17 or 18) experienced an onset of GBS 14-31 days after vaccination.[8] Although the timing of the onset of neurological symptoms (within the first month of vaccination) was alarming, it was not immediately known if there was a sound causal relationship between Menactra vaccination and GBS, as the six reported cases of GBS among approximately 2.5 million doses of Menactra distributed nationally is a rate similar to what might have been expected to occur by chance alone.[9]

The CDC and American Academy of Pediatrics (AAP) both continue to recommend Menactra administration for all 11 and 12 year olds at the pre-adolescent visit.[10]

Florida's public school vaccination schedule

In Florida, the following immunizations are required by age and school grade:[11]

Immunizations Required for Preschool Entry (age-appropriate doses as are medically indicated):

- Diphtheria-Tetanus-Pertussis Series
- Haemophilus influenzae type b (Hib)
- Hepatitis B
- Measles-Mumps-Rubella (MMR)
- Polio Series
- Varicella

Immunizations Required for Kindergarten Entry:

- Diphtheria-Tetanus-Pertussis Series
- Hepatitis B Series
- Measles-Mumps-Rubella (two doses of Measles vaccine, preferably as MMR)
- Polio Series
- Varicella

Immunizations Required for 7th Grade Entry:

- Hepatitis B Series

[6] *FDA and CDC Issue Alert on Menactra Meningococcal Vaccine and Guillain Barre Syndrome*, September 30, 2005, U.S. Food and Drug Administration, available at http://www.fda.gov/bbs/topics/NEWS/2005/NEW01238.html.

[7] According to the American Academy of Pediatrics and the National Institute of Neurological Disorders and Stroke, GBS is a severe neurological disorder causing weakness of the body's extremities as a result of an inflammatory demyelination of peripheral nerves. This weakness can intensify rapidly, rendering certain muscles useless and, when severe, leave a patient almost totally paralyzed. Although anyone can be affected by GBS – the disease can occur at any age and both sexes are equally susceptible to onset – the incidence rate is only about one person in 100,000. Presently, there are no known cures for GBS, although several therapies (including plasma exchange and high-dose immunoglobulin therapy) are utilized to accelerate recovery. Recovery periods for patients experiencing GBS are varied and can range from a few weeks to a few years, although roughly 30 percent of patients experience residual weakness after 3 years. A small proportion of patients die, and 20 percent of hospitalized patients can have prolonged disability.

[8] *Guillain-Barre Syndrome Among Adolescents Who Received Meningococcal Conjugate Vaccine Factsheet*, November 9, 2005, U.S. Food and Drug Administration, available at http://www.fda.gov/bbs/topics/NEWS/2005/NEW01238.html.

[9] Morbidity and Mortality Weekly Report, *Guillain-Barre Syndrome Among Recipients of Menactra Meningococcal Conjugate Vaccine – United States, June-July 2005*, October 6, 2005, Department of Health and Human Services Centers for Disease Control and Prevention, available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm54d1006a1.htm. Although the number of doses distributed is known, the precise number of administered doses is not.

[10] Ibid.

[11] *Vaccine Information Florida Vaccine Requirements*, National Network for Immunization Information, available at http://www.immunizationinfo.org/vaccineInfo/disease_stateinfo.cfv; *Immunization and Record Requirements*, available at http://www.doh.state.fl.us/disease_ctrl/immune/school.pdf

Second Dose of Measles Vaccine (preferably MMR vaccine)
Tetanus-Diphtheria Booster

Note: Since the Hepatitis B Series and Second Dose of Measles Vaccine were added to the kindergarten immunization schedule, students are not required to receive these vaccinations for 7th grade entry, unless they were not obtained previously.

Immunizations required for college/university students:
MR, M2 (All freshman and new enrollees in public universities)
Meningococcal (All college/university students who live in dorms, or must sign waiver)

Immunizations Required for Child Care and/or Family Day Care (up-to-date for age):
Diphtheria-Tetanus-Pertussis
Haemophilus influenzae type b
Measles-Mumps-Rubella
Polio
Varicella

While school districts and private schools are not currently required to provide information to parents regarding specific diseases or vaccinations, they regularly communicate with parents on a variety of topics including required immunizations and health screenings. All Florida postsecondary educational institutions must provide detailed information concerning the risks associated with meningococcal meningitis and its associated vaccines to every student or to the student's parent if the student is a minor. As noted above, all Florida college and university students who live in campus dormitories are required to be immunized against meningococcal disease or decline the immunization by signing a waiver.[12]

Proposed Changes

The bill requires each district school board and private school governing body to provide every student's parent with detailed information about the causes, symptoms and transmission of meningococcal disease, and about the availability, effectiveness, and contraindications associated with recommended vaccines. The information is to be provided in accordance with DOH recommendations.

The bill also requires DOH to adopt rules that specify the age or grade level of students for whom such information shall be provided. These rules are to be consistent with recommendations of the Advisory Committee on Immunization Practices (ACIP) concerning the appropriate age for vaccine administration.

The bill requires DOH to make available to school districts and private school governing authorities, information concerning the causes, symptoms, and transmission of meningococcal disease; the risks associated with the disease; and the availability, effectiveness and contraindications of its associated vaccines.

The bill also requires each school district and private school governing body shall determine the means and methods of providing this information to the student's parent.

C. SECTION DIRECTORY:

Section 1. Amends section 1003.22(10), Florida Statutes, relating to school-entry health examinations; creates new paragraph (c); requires district school board and private school governing authorities to provide every student's parent specified information about meningococcal disease in accordance with DOH recommendations; requires DOH to adopt rules consistent with recommendations of ACIP;

[12] s. 1006.69, F.S.

requires district school boards and private school governing authorities to determine means and methods for providing information to students' parent.

Section 2. Provides an effective date of July 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Although the bill does not require adolescent vaccination against meningococcal disease, the Department of Health reports there is a potential cost to parents or private health insurance companies to cover the costs of vaccine and administration of vaccine for those parents who choose to have adolescents vaccinated. The department estimates the market price of the vaccine to be $75-$100 per dose.

Private school governing authorities may incur minor costs related to the provision of information about meningococcal disease to students' parents. However, the bill allows the private school governing body to determine the method for providing such information, so they may select the most cost-effective method.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not appear to require counties or municipalities to spend funds or to take actions requiring the expenditure of funds; reduce the authority that cities or counties have to raise revenues in the aggregate; or reduce the percentage of a state tax shared with cities or counties.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

House Bill 127 CS requires the Department of Health to adopt rules specifying the age or grade level of students to receive the information regarding meningococcal disease, consistent with recommendations of the CDC.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Lines 36-47: It is unclear whether DOH is required to adopt rules addressing the causes, symptoms, etc. of meningococcal disease and its associated vaccine, or merely to make such information available to schools independent of its rulemaking authority.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

At its January 11, 2006 meeting, the Committee on Elder & Long-Term Care adopted an amendment to House Bill 127. The amendment removed Section 1 of the bill, requiring assisted living facilities to implement a program to offer immunizations against influenza and pneumococcal bacteria to all residents age 65 and older, in its entirety.

The Committee favorably reported a Committee Substitute. This analysis is drafted to the Committee Substitute.