SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

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

BILL: CS/SB 1628

SPONSOR: Health, Aging and Long-Term Care Committee and Senator Pruitt

SUBJECT: Immunizations/Meningococcal Disease

DATE: February 15, 2002 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Harkey	Wilson	HC	Favorable/CS
2.			ED	
3.			AED	
4.			AP	
5.				
6.				

I. Summary:

The bill requires a postsecondary education institution to provide every student who has been accepted for admission detailed information about the risks associated with meningococcal disease, diphtheria, tetanus, and hepatitis B. A student who lives in on-campus housing must provide documentation of vaccination against the diseases or sign a waiver acknowledging receipt of the information. Postsecondary institutions are not required to provide or pay for vaccinations against meningitis, diphtheria, tetanus, and hepatitis B.

This bill creates one unnumbered section of law.

II. Present Situation:

Meningitis

According to the U.S. Centers for Disease Control and Prevention (CDC), "Meningitis is an infection of the fluid of a person's spinal cord and the fluid that surrounds the brain. People sometimes refer to it as spinal meningitis. Meningitis is usually caused by a viral or bacterial infection. Knowing whether meningitis is caused by a virus or bacterium is important because the severity of illness and the treatment differ. Viral meningitis is generally less severe and resolves without specific treatment, while bacterial meningitis can be quite severe and may result in brain damage, hearing loss, or learning disability. For bacterial meningitis, it is also important to know which type of bacteria is causing the meningitis because antibiotics can prevent some types from spreading and infecting other people. Before the 1990s, *Haemophilus influenzae* type b (Hib) was the leading cause of bacterial meningitis, but new vaccines being given to all children as part of their routine immunizations have reduced the occurrence of invasive disease

due to *H. influenzae*. Today, *Streptococcus pneumoniae* and *Neisseria meningitidis* are the leading causes of bacterial meningitis."

Approximately 3,000 cases of meningococcal disease occur each year in the United States. Even with antibiotic treatment, 10-13 percent of patients die. For approximately 10 percent of those who survive, severe impairment follows the disease, which could include mental retardation, hearing loss and loss of limbs.

In a press release from the CDC, dated October 20, 1999, the Advisory Committee on Immunization Practices (ACIP) announced modified guidelines for use of the polysaccharide meningococcal vaccine to prevent bacterial meningitis, particularly for college freshmen who live in dormitories. The press release contained the following statement:

> At its October 20, 1999 meeting, the ACIP, citing results of two CDC studies done in 1998 which identified the slightly higher risk among freshman dormitory residents, recommended that those who provide medical care to this group give information to students and their parents about meningococcal disease and the benefits of vaccination. Vaccination should be provided or made easily available to those freshmen who wish to reduce their risk of disease. Other undergraduate students wishing to reduce their risk of meningococcal disease can also choose to be vaccinated.
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> The currently available vaccine protects against some types (serogroups) of the bacterium *Neisseria meningitidis* (also called meningococcus), an important cause of bacterial meningitis and sepsis in children and young adults in the United States. A single dose of the vaccine is recommended, and vaccination will decrease the risk of disease caused by *N. meningitidis* serogroups A, C, Y, and W-135. However, vaccination will not totally eliminate risk of the disease because the vaccine does not protect against serogroup B and because, although it is highly effective against serogroups C and Y, it still does not confer 100 percent protection against these serogroups. In 1998-1999, serogroups C and Y caused about 70 percent of cases among college students.

A vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions. The CDC states that the risk of the meningococcal vaccine causing serious harm, or death, is extremely small and getting meningococcal vaccine is much safer than getting the disease. Some people who get meningococcal vaccine have mild side effects, such as redness or pain where the shot was given. These symptoms usually last for 1-2 days. A small percentage of people who receive the vaccine develop a fever. If a serious allergic reaction occurred, it would happen within a few minutes to a few hours after the shot. Signs of a serious allergic reaction can include difficulty breathing, weakness, hoarseness or wheezing, a fast heart beat, hives, dizziness, paleness, or swelling of the throat. A person experiencing a severe allergic reaction should call or see a doctor right away.

Diphtheria

According to the CDC:

> Diphtheria is an acute, toxin-mediated disease caused by *Corynebacterium diphtheriae*….

C. diphtheriae is an aerobic gram-positive bacillus. Toxin-production (toxigenicity) occurs only when the bacillus is itself infected (lysogenized) by a specific virus (bacteriophage) carrying the genetic information for the toxin (tox gene). Only toxigenic strains can cause severe disease….

Susceptible persons may acquire toxigenic diphtheria bacilli in the nasopharynx. The organism produces a toxin that inhibits cellular protein synthesis and is responsible for local tissue destruction and membrane formation. The toxin produced at the site of the membrane is absorbed into the bloodstream and then distributed to the tissues of the body. The toxin is responsible for the major complications of myocarditis and neuritis and can also cause low platelet counts (thrombocytopenia) and protein in the urine (proteinuria)….

Most complications of diphtheria, including death, are attributable to effects of the toxin. The severity of the disease and complications are generally related to the extent of local disease. The toxin, when absorbed, affects organs and tissues distant from the site of invasion. The most frequent complications of diphtheria are:

Myocarditis
Abnormal cardiac rhythms can occur early in the course of the illness or weeks later, and can lead to heart failure. If myocarditis occurs early, it is often fatal.

Neuritis
This complication most often affects motor nerves and usually clears completely. Paralysis of the soft palate is most frequent during the third week of illness. Eye muscles, limbs, and diaphragm paralysis can occur after the fifth week. Secondary pneumonia and respiratory failure may result from diaphragmatic paralysis.

Other complications include otitis media and respiratory insufficiency due to airway obstruction, especially in infants.

Death
The overall case-fatality rate for diphtheria is 5%-10%, with higher death rates (up to 20%) in persons <5 and >40 years of age. The case-fatality rate for diphtheria has changed very little during the last 50 years.

Tetanus

According to the CDC:

Tetanus is an acute, often fatal, disease caused by an exotoxin produced by *Clostridium tetani*. It is characterized by generalized rigidity and convulsive spasms of skeletal muscles. The muscle stiffness usually involves the jaw (lockjaw) and neck and then becomes generalized….

C. tetani usually enters the body through a wound. In the presence of anaerobic (low oxygen) conditions, the spores germinate. Toxins, including tetanospasmin, are produced,

> and disseminated via blood and lymphatics. Toxins act at several sites within the central nervous system, including peripheral motor end plates, spinal cord, brain, and sympathetic nervous system. The typical clinical manifestations of tetanus are caused when tetanus toxin interferes with release of neurotransmitters, blocking inhibitor impulses. This leads to unopposed muscle contraction and spasm. Seizures may occur, and the autonomic nervous system may also be affected….
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> Approximately 30% of reported cases are fatal. In the United States, most deaths occur in persons >50 years of age. In about 20% of tetanus deaths, no obvious pathology is identified and death is attributed to the direct effects of tetanus toxin. The course usually lasts several weeks, with gradual decline over time.

Td Vaccine

According to the CDC, "Diphtheria toxoid is available combined with tetanus as pediatric DT or adult Td, and with both tetanus toxoid and acellular pertussis vaccine as DtaP."

The CDC recommends the vaccination as follows:

> Td is the vaccine of choice for children 7 years old and older, and for adults. A primary series is three doses. The first two doses should be separated by at least 4 weeks, and the third dose given 6-12 months after the second. A booster dose of Td should be given every 10 years.

Adverse reactions to the vaccination can include a severe local reaction, particularly in individuals who have had multiple prior boosters. Severe systemic reactions are rare, but urticaria, anaphylaxis, or neurologic complications have been reported.

Hepatitis B

According to the CDC, "Hepatitis B is a serious disease caused by a virus that attacks the liver. The virus, which is called hepatitis B virus (HBV), can cause lifelong infection, cirrhosis (scarring) of the liver, liver cancer, liver failure, and death. Hepatitis B vaccine is available for all age groups to prevent hepatitis B virus infection."

Immunization Requirements for Middle and High School Students

Under rule 64D-3.011, F.A.C., prior to admittance to a public or nonpublic school, grades preschool through grade 12, a student must present a certificate of immunization for prevention of diphtheria, pertussis, tetanus, poliomyelitis, rubeola, rubella, and mumps. Prior to entering 7th grade, students must present evidence of completion of the hepatitis B series, a second dose of measles vaccine, and a tetanus-diphtheria booster. However, there is a national shortage of the Td vaccine, and as a result of the shortage, the Department of Health authorized a one-year temporary medical exemption (TME) for middle school students subject to the requirement. In January 2002, the DOH authorized an extension of the TMEs because of the continuing shortage. The CDC estimates that the shortage may not be resolved until August 2002.

Immunization Requirements for Public Colleges and Universities

Students of public universities and colleges are required to provide proof of immunization for measles and rubella before acceptance into an institution. This requirement is established in Rule 6C-6.001(5), Florida Administrative Code (FAC). Many private universities and community colleges that are located in Florida, which are not governed by the State Board of Education, have also adopted policies requiring proof of measles and rubella immunization prior to admission. However, there are no requirements for vaccination against meningococcal meningitis prior to acceptance into a postsecondary educational institution.

The population of students in colleges and private universities who live in dormitories is not known. The dormitory capacity of state universities is given below:

Dormitory capacity at state universities, 1999-2000

University of Florida	6,638
Florida State University	4,081
Florida A&M University	2,973
University of South Florida	2,965
Florida Atlantic University	1,336
University of West Florida	1,048
University of Central Florida	2,091
Florida International University	1,796
University of North Florida	1,530
Florida Gulf Coast University	520
Total	24,978

III. Effect of Proposed Changes:

The bill requires a postsecondary education institution to provide every student who has been accepted for admission detailed information about the risks associated with meningococcal disease, diphtheria, tetanus, and hepatitis B. A student who lives in on-campus housing must provide documentation of vaccination against the diseases or provide a signed waiver acknowledging receipt of the information. If the student is 18 years of age or older, he or she must sign the waiver; if the student is a minor, his or her parent or guardian signs a waiver.

The bill states that the institutions of higher education are not required to provide or pay for the vaccinations.

The bill takes effect July 1, 2002.

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 Art. VII, s. 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 Art. I, s. 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

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

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Private universities and colleges would incur the cost of providing information to individuals residing in on-campus housing.

Students would incur the cost of the vaccinations for meningitis, diphtheria, tetanus, and hepatitis B.

The Department of Health estimates that each student's meningitis vaccination would cost $88.00.

The market price for a Td vaccine is approximately $8 per dose, but the cost varies because of the national shortage of the vaccine.

The market price of a single dose of the hepatitis B vaccine is approximately $24.24, and three doses are required to complete the series.

C. Government Sector Impact:

State universities, colleges, and community colleges would incur the cost of providing information to all students and providing waiver forms to individuals residing in on-campus housing.

VI. Technical Deficiencies:

The bill requires a postsecondary institution to inform every student who has been accepted for admission of the risks associated with the specified diseases. It is not clear whether the institution would have to inform every student on campus or only first-time-in-college students.

VII. Related Issues:

A middle school student who received a Td vaccination in 7th grade would not need a booster vaccination for 10 years, and thus would not be likely to need the immunization upon entering college five years after completing the 7th grade.

VIII. Amendments:

None.