

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide limited government ---

- The bill requires each licensed assisted living facility to implement a program to offer immunizations against influenza viruses to all residents aged 65 or older.
- The bill 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:

Immunizations in Assisted Living Facilities

Assisted living facilities (ALF) are licensed under Part III of Chapter 400, F.S.¹ Currently, there is no requirement that ALF offer immunizations against the influenza virus to their residents.

Influenza, commonly called the "flu," is caused by the influenza virus that infects the respiratory tract. The virus is typically spread from person to person when an infected person coughs or sneezes the virus into the air. Influenza can cause severe illness and lead to serious and life-threatening complications in all age groups. Complications such as bacterial pneumonia, dehydration, and worsening of underlying chronic conditions (such as congestive heart disease and asthma) occur most often in persons who are particularly vulnerable, such as elderly persons and persons with chronic conditions.²

Flu is a major cause of illness and death in the United States and leads to over 200,000 hospitalizations and approximately 36,000 deaths each year, according to the Centers for Disease Control and Prevention (CDC).³

Vaccines are effective in protecting individuals against illness or serious complications of flu, particularly those who are at high risk for developing serious complications from the disease. The Advisory Committee on Immunization Practices of CDC (ACIP) recommends that, when vaccine is available, persons in high-risk groups including individuals aged 65 or older, and people with chronic diseases of the heart, lung, or kidneys, diabetes, immunosuppression, or severe forms of anemia, should be vaccinated against the flu. ACIP also recommends that residents of nursing homes and other chronic-care facilities, children receiving long-term aspirin therapy, and any person who is in close or frequent contact with anyone in the high-risk group, such as health care personnel and volunteers, be vaccinated.⁴ The CDC recommends that the optimal time to be vaccinated against flu is the fall.⁵

¹ The Assisted Living Facilities Act, ss. 400.401 – 400.454, F.S.

² See *Fact Sheet Influenza (Flu) Key Facts about the Flu*, November 10, 2004, Department of Health and Human Services Centers for Disease Control and Prevention; *Flu*, January 2005, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, available at <http://www.niaid.nih.gov/factsheets/flu.htm>

³ *Influenza: The Disease*, November 15, 2004, Department of Health and Human Services Centers for Disease Control and Prevention, available at <http://www.cdc.gov/flu/about/disease.htm>

⁴ Because of the influenza vaccine shortage during the 2004-2005 flu season, the CDC twice revised its recommendations regarding who should receive the vaccine. Persons age 65 and older and residents of nursing homes and long-term care facilities were always in the highest priority groups. See fn.2, *Recommended Adult Immunization Schedule United States October 2004-September 2005, Summary of Recommendation Published by the Advisory*

Medicare coverage for flu shots for the elderly began in 1993. Flu shots are available at no cost to individuals enrolled in Medicare Part B from physicians or providers who bill Medicare. If patients receive their flu vaccines from physicians or providers who do not bill Medicare, they may be reimbursed (about \$18) by Medicare.⁶ The Medicaid program covers costs for flu vaccine and administration for Medicaid patients who are residents of nursing homes and long-term care facilities who are not the recipients of Medicare benefits.

An immunization requirement similar to that proposed in the CS is imposed on licensed hospitals pursuant to s. 381.005(2), F.S., as part of the Department of Health's primary and preventative health services mission.⁷

CS for HB 1073 creates new subsection (3) of s. 381.005, .F.S., and requires each licensed ALF to implement a program to offer immunizations against influenza viruses to all residents aged 65 or older in accordance with recommendations of ACIP of the CDC. This program is to be carried out between October 1 (earlier if the vaccine is available) and February 1 of each year, subject to adequate vaccine supplies and subject to the clinical judgment of the responsible practitioner. The CS exempts ALF having ten or fewer residents, and it requires the Department of Health to provide a notice to each affected ALF by September 1 of each year reminding the ALF of their responsibilities under the section.

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 15 percent of the 2,600 cases of meningococcal meningitis that are reported in the U.S. each year.

The largest incidence of the disease is in children under age 5, with a second peak in children and young adults between the ages 15 and 24.⁸

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*.⁹

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 (also known as MCV-4), licensed in 2005.¹⁰

Committee on Immunization Practices, Department of Health and Human Services Centers for Disease Control and Prevention, available at <http://www.immunization.org/downloads/adult-schedule.pdf>

⁵ *Fact Sheet Influenza (Flu) Key Facts about the Flu Vaccine*, January 27, 2005, Department of Health and Human Services Centers for Disease Control and Prevention, available at <http://www.cdc.gov/flu/protect/pdf/vaccinekeyfacts.pdf>

⁶ *Important Information About Medicare Payment for Flu Shots*, available at <http://medicare.gov/health/flipayments.asp>

⁷ S. 381.005(2), F.S., requires hospitals licensed under Chapter 395 to implement a program to offer immunizations against influenza and pneumococcal bacteria to all patients aged 65 and older.

⁸ *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

⁹ *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

¹⁰ There is no licensed vaccine for Serogroup B in the U.S. *Vaccine Information Meningococcal Disease*.

With FDA's approval of MCV4, ACIP and CDC on February 10, 2005, recommended routine vaccination of children ages 11-14 or before high school entry

as the most effective strategy towards reducing meningococcal disease incidence in adolescence and young adulthood. Within 3 years, the goal is routine vaccination with MCV4 of all adolescents beginning at 11 years of age. ACIP recognizes that vaccine supply may be an issue in the first few years after licensure of MCV4. Other adolescents who wish to decrease their risk of meningococcal disease may elect to receive vaccine.¹¹

In Florida, the following immunizations are required by age and school grade:¹²

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

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

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

¹¹ *Meningococcal Conjugate Vaccine, ACIP Recommends Meningococcal Vaccine for Adolescents and College Freshman*, National Immunization Program Centers for Disease Control and Prevention, available at http://www.cdc.gov/nip/vaccine/meningitis/mcs4/mcv4_acip.htm

¹² *Vaccine Information Florida Vaccine Requirements*, National Network for Immunization Information, available at http://www.immunizationinfo.org/vaccineInfo/disease_stateinfo.cfy; *Immunization and Record Requirements*, available at http://www.doh.state.fl.us/disease_ctrl/immune/school.pdf

who live in campus dormitories are required to be immunized against meningococcal disease or decline the immunization by signing a waiver.¹³

HB 1073 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.

DOH is 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 ACIP concerning the appropriate age for vaccine administration.

DOH shall 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.

Each school district and private school governing body shall determine the means and methods of providing this information to the student's parent.

The bill is effective July 1, 2005.

C. SECTION DIRECTORY:

Section 1: Amends s. 381.005, F.S.; creates new subsection (3); requires each licensed ALF to implement a program to offer immunizations against influenza viruses to all residents aged 65 or older in accordance with certain recommendations; exempts certain ALF; requires DOH to provide notices.

Section 2: Amends s. 1003.22(10), F.S., 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; requires district school boards and private school governing authorities to determine means and methods for providing information to students' parent.

Section 3: Provides an effective date of July 1, 2005.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

¹³ S. 1006.69, F.S.

2. Expenditures:

Meningococcal Disease and Immunization

School districts may incur costs related to the provision of information about meningococcal disease to students' parents.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Immunizations in Assisted Living Facilities

Assisted living facilities will incur additional costs to design and implement the program required by the bill.

Meningococcal Disease and Immunization

Private school governing authorities may incur costs related to the provision of information about meningococcal disease to students' parents.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

The bill does not appear to require a city or county to expend funds or to take any action requiring the expenditure of funds.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

Meningococcal Disease and Immunization

The bill requires DOH 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:

Meningococcal Disease and Immunization

Lines 54-65: 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 that information available to schools outside of rulemaking.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

At its April 6, 2005, meeting, the Committee on Elder & Long-Term Care adopted an amendment to HB 1073. The amendment locates the requirement for assisted living facilities to implement a program to offer influenza vaccines in newly-created subsection (3) of s. 381.005, F.S., to parallel a similar requirement for hospitals. In addition, the amendment exempts ALF having ten or fewer residents, and it requires the Department of Health to provide a notice to each affected ALF by September 1 of each year reminding the ALF of their responsibilities under the section. The Committee favorably reported the Committee Substitute.

This analysis is drawn to the Committee Substitute.