

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 127

Immunizations

SPONSOR(S): Hays

TIED BILLS:

IDEN./SIM. BILLS: SB 1160

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Elder & Long-Term Care Committee		DePalma	Walsh
2) PreK-12 Committee			
3) Health Care Appropriations Committee			
4) Health & Families Council			
5) _____			

SUMMARY ANALYSIS

HB 127 requires each licensed assisted living facility to implement a program to offer immunizations against influenza and pneumococcal bacteria to all residents age 65 or older.

The bill 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 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' parent.

The effective date is July 1, 2006.

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 and pneumococcal bacteria to all residents age 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

Influenza

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. Transmission rates are greatest for individuals in highly populated areas, such as in schools and residences with crowded living conditions. 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, those living in nursing homes and other long-term care facilities, 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 individuals 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 age 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

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

² See *Fact Sheet Influenza (Flu) Key Facts about the Flu*, September 28, 2005, 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>.

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

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 Medicare provides coverage for one influenza vaccination per year, but additional vaccinations may be available if reasonable and medically necessary.⁷ 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 bill 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.⁸ Similarly, s. 400.141(22) directs all licensed nursing home facilities to provide vaccinations against influenza to all consenting residents, but notes that residents aren't foreclosed from pursuing influenza vaccination from personal physicians if proper documentation is submitted.⁹

Pneumococcal Disease

Pneumococcal pneumonia is a lower respiratory tract infection caused by the bacterium *Streptococcus pneumoniae* which colonizes in the lungs, but can potentially invade the bloodstream (causing bacteremia) and the tissues and fluids surrounding the brain and spinal cord (resulting in a form of meningitis, an inflammation of the tissues and fluids surrounding the brain and spinal cord).¹⁰ "Pneumonia" is not a single disease, but rather can have over 30 different causes. The five main causes of pneumonia in the U.S. are bacteria, viruses, mycoplasmas, chemical exposure, and exposure to other infectious agents such as fungi (including pneumocystis).¹¹

Pneumococcal pneumonia is the most common cause of bacterial pneumonia acquired outside of hospitals,¹² as CDC estimates indicate that *S. pneumoniae* causes 500,000 cases of pneumonia and is blamed for 40,000 deaths annually in the United States.¹³ This mortality figure is the highest among vaccine-preventable bacterial diseases in the U.S.¹⁴ Pneumonia and influenza together represent the

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 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*, September 28, 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/flupayments.asp>

⁷ *Adult Immunizations*, May 2005, Centers for Medicare and Medicaid Services, available at http://new.cms.hhs.gov/MedlearnProducts/downloads/Adult_Immunization_06-08-05.pdf.

⁸ 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 age 65 and older.

⁹ S. 400.141(22), F.S.

¹⁰ *Facts About Pneumococcal Disease for Adults*, July 2002, National Coalition for Adult Immunization, available at <http://www.nfid.org/factsheets/pneuadult.html>.

¹¹ *Pneumonia*, October 2002, American Lung Association, available at <http://www.lungusa.org/site/pp.asp?c=dvLUK90OE&b=356921>.

¹² *Pneumonia Fact Sheet*, June 2005, American Lung Association, available at <http://www.lungusa.org/site/pp.asp?c=dvLUK90OE&b=35692>.

¹³ *Pneumococcal Pneumonia*, updated December 13, 2004, Department of Health and Human Services National Institute of Allergy and Infectious Diseases, available at <http://www.niaid.nih.gov/factsheets/pneumonia.htm>.

¹⁴ Morbidity and Mortality Weekly Report, *Prevention of Pneumococcal Disease: Recommendations of the Advisory Committee on Immunization Practices*, April 4, 1997, Department of Health and Human Services Centers for Disease Control and Prevention, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00047135.htm>.

seventh leading cause of death in the United States,¹⁵ and the fifth leading cause of death among adults age 65 and older.¹⁶ Additionally, *S. pneumoniae* is annually responsible for 60,000 cases of bacteremia and 3,300 cases of meningitis.¹⁷

The pneumococcal polysaccharide vaccine (PPV) effectively protects against 23 types of *S. pneumoniae* that are responsible for causing greater than 90% of all pneumococcal disease cases,¹⁸ and is effective in approximately 80 percent of healthy adults.¹⁹ The vaccination can be given at any time of the year, and most people only need one lifetime dose.²⁰ However, revaccination is recommended for adults age 65 and older who got their first dose when they were under 65, if five or more years have passed since the original vaccination.²¹ In addition to recommending that all adults age 65 and older and those with chronic heart or liver disease be vaccinated, the CDC also recommends that all nursing home patients and others admitted to long-term care facilities should be vaccinated against pneumococcal disease.²²

The Medicare program has covered PPV immunizations since July 1, 1983. Presently, the pneumococcal vaccine is fully covered by Medicare Part B if the healthcare provider accepts the Medicare-approved amount.²³ Although coverage rates for pneumococcal vaccination among adults age 65 and older experienced a sharp increase during the 1990s, the rates have stabilized in recent years.²⁴

An immunization requirement similar to the one proposed in HB 127 is found in s. 400.121(23), F.S., and directs licensed nursing facilities to assess their residents for PPV immunization eligibility within 5 days of admission, and vaccinate those eligible residents with the PPV vaccine within 60 days, in accordance with CDC recommendations.²⁵ Moreover, that section also indicates that residents may elect to receive PPV immunization from a personal physician if proper documentation is submitted.²⁶ However, unlike the requirement for provision of influenza vaccination in s. 400.121(22), F.S., this section does not make reference to obtaining a resident's consent prior to PPV immunization. Despite this, both sections note that the immunizations required are "subject to exemptions for medical contraindications and religious or personal beliefs."²⁷

Effect of Proposed Bill

The bill amends s. 400.426, F.S., and requires each licensed ALF to implement a program to offer immunizations against influenza and pneumococcal bacteria to all residents age 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

¹⁵ *Pneumonia Fact Sheet*, American Lung Association.

¹⁶ *Facts About Pneumococcal Disease for Adults*, National Coalition for Adult Immunization.

¹⁷ *Ibid.*

¹⁸ *Facts About Pneumococcal Disease for Adults*, National Coalition for Adult Immunization.

¹⁹ *Pneumonia Fact Sheet*, American Lung Association.

²⁰ *Pneumococcal Vaccine: Publications, Questions & Answers Etc.*, updated February 6, 2004, Department of Health and Human Services Centers for Disease Control and Prevention, available at <http://www.cdc.gov/nip/vaccine/pneumo/pneumo-pubs.htm>.

²¹ *Pneumococcal Polysaccharide Vaccine: What You Need to Know*, July 29, 1997, Department of Health and Human Services Centers for Disease Control and Prevention, available at <http://www.cdc.gov/nip/publications/VIS/vis-ppv.pdf>.

²² *Pneumococcal Polysaccharide Vaccine (PPV 23): CDC Answers Your Questions*, May 2005, Immunization Action Coalition, available at <http://www.immunize.org>.

²³ *Facts About Pneumococcal Disease for Adults*, National Coalition for Adult Immunization. See also *2005-2006 Immunizers' Question & Answer Guide to Medicare Coverage of Influenza and Pneumococcal Vaccinations*, September 25, 2005, Centers for Medicare and Medicaid Services, available at <http://new.cms.hhs.gov/AdultImmunizations/downloads/2005-2006QAGuide.pdf>.

²⁴ *2005-2006 Immunizers' Question & Answer Guide to Medicare Coverage of Influenza and Pneumococcal Vaccinations*, Centers for Medicare and Medicaid Services

²⁵ S. 400.141(23), F.S.

²⁶ *Ibid.*

²⁷ Ss. 400.121(22), (23), F.S.

supplies and subject to the clinical judgment of the responsible practitioner. The bill exempts ALF having ten or fewer residents, and it requires the Department of Elder Affairs (DOEA) 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 14 percent of the 1,400-2,800 cases of meningococcal meningitis that are reported in the U.S. each year.²⁸

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 24.²⁹

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*.³⁰

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.³¹

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

to 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.³²

In September 2005, CDC and the U.S. Food and Drug Administration (FDA) issued an alert³³ after reports made to the Vaccine Adverse Event Reporting System (VAERS) indicated that five adolescents had developed Guillain-Barre Syndrome³⁴ (GBS) following administration of the Menactra vaccine. By

²⁸ 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>.

²⁹ *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.

³⁰ *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.

³¹ There is no licensed vaccine for Serogroup B in the U.S. *Vaccine Information Meningococcal Disease*.

³² 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>.

³³ *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>.

³⁴ 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

November 2005, six Menactra recipients (all ages 17 or 18) experienced an onset of GBS 14-31 days after vaccination.³⁵ 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.³⁶

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.³⁷

Florida's public school vaccination schedule

In Florida, the following immunizations are required by age and school grade:³⁸

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

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.

³⁵ *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>.

³⁶ 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.

³⁷ Ibid.

³⁸ *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

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 who live in campus dormitories are required to be immunized against meningococcal disease or decline the immunization by signing a waiver.³⁹

Effect of Proposed Bill

HB 127 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, 2006.

C. SECTION DIRECTORY:

Section 1: Amends s. 400.426, F.S.; creates new subsection (13); requires each licensed ALF to implement a program to offer immunizations against influenza and pneumococcal bacteria to all residents age 65 or older in accordance with certain recommendations; requires DOEA to provide notices to ALF.

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, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

³⁹ S. 1006.69, F.S.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

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:

Line 6: "Department of Health" should be "Agency for Health Care Administration". As the agency charged with licensure of ALF, it would be more efficient for AHCA to send the required reminder notices. Similarly, at line 36, "department" should be "agency".

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.

As noted in the above analysis, the CDC currently recommends a single dose of PPV immunization, with revaccination recommended for adults age 65 and older who received an initial PPV dose when they were under 65, if five or more years have passed since the original vaccination. It is suggested that the bill be amended to reflect the recommendations and indicate that, during the October-February vaccination period, ALF resident *assessments* for PPV eligibility will be made.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES