

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Promote personal responsibility—The bill provides individuals and families with increased access to immunizations services and health insurance immunizations options.

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 in accordance with recommendations of the Advisory Committee on Immunizations Practices and the Centers for Disease Control and Prevention. The bill creates the Commission on the Study of Biotech Competitiveness within the Governor's Office of Tourism, Trade & Economic Development and provides duties and responsibilities.

B. EFFECT OF PROPOSED CHANGES:

House Bill 543 addresses access to immunization services for children and adults and provides a comprehensive approach to preventing the spread of certain diseases through increased access to immunization services. The bill provides a mechanism to coordinate immunization programs and information including vaccine and disease education programs, enhance health care provider flexibility, and encourage vaccine production and distribution in Florida. The intended effect of this bill is to prevent the spread of communicable diseases by improving access to immunization services.

The bill amends s. 400.426, F.S., and 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 in accordance with recommendations of the Advisory Committee on Immunizations Practices and the Centers for Disease Control and Prevention. This program is to be carried out between October 1 and February 1 or each year, subject to adequate vaccine supplies and subject to the responsible practitioner's clinical judgment. The bill exempts ALFs having ten or fewer residents and requires the Department of Health to provide a notice to each affected ALF.

The bill amends s. 465.003(13), F.S., to revise the definition of the "practice of the profession of pharmacy" to include the administering immunizations to adults by a pharmacist within the framework of an established protocol under a supervisory practitioner who is a Florida-licensed medical or osteopathic physician or by written agreement with a county health department. Each protocol must contain specific procedures to address any unforeseen allergic reaction to an immunization.

A pharmacist may not enter into a protocol unless he or she maintains at least \$200,000 of professional liability insurance and not until the pharmacist has completed training in immunizations as required by the Board of Pharmacy. The decision by a supervisory practitioner to enter into such a protocol is a professional decision of the practitioner, and a person may not interfere with a supervisory practitioner's decision as to whether to enter into such a protocol. A pharmacist may not enter into a protocol to administer immunizations while acting as an employee without the written approval of the owner of the pharmacy.

Any pharmacist seeking to immunize patients must be certified to administer immunizations under a certification program approved by the Board of Pharmacy upon consultation with the Board of Medicine. The certification program must, at a minimum, require that a pharmacist attend at least 20 hours of continuing education classes approved by the Board of Pharmacy. The program must have a curriculum of instruction concerning the safe and effective administration of immunizations, including, but not limited to, potential allergic reactions to immunizations.

The bill creates s. 627.64194 Coverage for Immunizations within Part VI of the Florida Insurance Code. This newly created statute would require accident or health insurers to offer optional coverage for immunizations, including those recommended or required for specific international travel. Further, the proposal would allow an insurer to charge an additional premium for immunization coverage and the coverage would not be subject to any deductible co-payment or coinsurance provisions.

Present Situation

Public and Private Schools Immunization Information

Sections 1002.23(7) (e) 2 and 1002.42 (6) (b) 2, F.S., specifies that public and private schools must provide every students' parents with information on the importance of school health and available immunizations and vaccinations, including, but not limited to:

- a recommended immunization schedule, in accordance with the United States Centers for Disease Control and Prevention recommendations; and
- detailed information regarding the causes, symptoms and transmission of meningococcal disease; and the availability, effectiveness, known contraindications and the appropriate age for the administration of any required or recommended vaccine against meningococcal disease, in accordance with the recommendations of the Advisory Committee on Immunizations Practices of the United States Center for Disease Control and Prevention.

Influenza Immunization

Influenza and pneumonia combined represent the fifth leading cause of death in the elderly. Influenza vaccine is the primary method for preventing influenza and its severe complications. Influenza immunization has been shown to be helpful in decreasing hospitalizations and deaths.¹

There are minimal adverse reactions or side effects associated with influenza vaccination. The most common adverse reactions to inactivated influenza vaccine are related to the body's response to the vaccine components at the site of injection. Common reactions may include inflammation at the injection site including fever, malaise, and muscle aches.² Serious immediate allergic reactions to inactivated influenza vaccines may occur within a few minutes to a few hours in individuals who likely have allergies to vaccine components. Immediate allergic reactions can appear mildly as itching and hives. In the severest form, reactions such as difficulty breathing, loss of blood pressure, and even death; however prompt medical treatment is usually effective. These potential side effects should be weighed against its benefits, which include prevention of serious illness, hospitalization, and death.

The influenza vaccine is contraindicated for people with a history of hypersensitivity to eggs or egg products or other components of influenza vaccines. As with all vaccines, it is prudent that recipients remain under observation for the first 15-30 minutes after the vaccine is injected. The purpose of this observation is to detect and treat any rare, serious allergic reactions.

Immunizations in Assisted Living Facilities

Influenza

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

¹ See 1999 RAND report prepared for the Centers for Medicare & Medicaid Services, "Interventions that increase Utilization of Medicare-Funded Preventive Services for Persons Age 65 and Older." www.cms.hhs.gov/healthyaging

² See "Prevention and control of influenza: Recommendations of the Advisory Committee on Immunization Practices," Morbidity and Mortality Weekly Report 51 (April 12, 2002).

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 conditions such as congestive heart disease and asthma occur most often in vulnerable persons including elderly persons, those living in nursing homes and other long-term care facilities, and persons with chronic conditions.

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 or frequent contact with anyone in the high-risk group, such as health care personnel and volunteers, be vaccinated.⁴

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. Medicare provides coverage for one influenza vaccination per year, but additional vaccinations may be available if reasonable and medically necessary. 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. Similarly, s. 400.141(22), F.S., directs all licensed nursing home facilities to provide vaccinations against influenza to all consenting residents. Residents may receive the immunization from his or her personal physician and provide proof of immunization to the facility.

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). “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).

Pneumococcal pneumonia is the most common cause of bacterial pneumonia acquired outside of hospitals, as CDC estimates indicate that *S. pneumoniae* causes 500,000 cases of pneumonia and is

³ See www.aphanet.org/pharmcare/immunofact.

⁴ Medicare and Medicaid Programs; conditions of Participation: Long-Term Care Facilities, and Home Health Agencies Final Rule to facilitate the delivery of adult vaccination in participating facilities for influenza and pneumococcal diseases, Federal Register, Vol. 67, No. 191, October 2, 2002.

blamed for 40,000 deaths annually in the United States.⁵ This mortality figure is the highest among vaccine-preventable bacterial diseases in the U.S.

Pharmacy Practice

Chapter 465, F.S., governs the practice of the profession of pharmacy. The Board of Pharmacy is authorized to adopt rules for duties conferred upon it under the pharmacy practice act. Section 465.003, F.S., defines the “practice of the profession of pharmacy” to include compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug; consulting concerning therapeutic values and interactions of patent and proprietary preparations, whether pursuant to prescriptions or in the absence and entirely independent of such prescriptions or orders; and other pharmaceutical services. “Other pharmaceutical services” means the monitoring of the patient’s drug therapy and assisting the patient in the management of his or her drug therapy, and includes review of the patient’s drug therapy and communication with the patient’s prescribing health care provider or the provider’s agent regarding the drug therapy. The practice of pharmacy also includes any other act, service, operation, research, or transaction incidental to, or forming a part of, any of the foregoing acts, requiring, involving, or employing the science or art of any branch of the pharmaceutical profession, study, or training, and expressly permits a pharmacist to transmit information from persons authorized to prescribe medicinal drugs to their patients.

As of February 22, 2005, 43 states allow pharmacists to immunize patients.⁶ Several of the states permit pharmacists to immunize for virtually any disease for which a vaccine is available.

According to studies published in the *International Journal of Pharmacy Practice and Pharmacotherapy*, pharmacists providing flu vaccinations increased vaccination rates in high risk patients by 74 percent. Standing orders are used in some states to authorize licensed practitioners to administer vaccinations, after assessment for contraindications, according to a physician-approved policy without the need for a physician’s order in nursing homes and hospitals.

Immunization Coverage

The state operates the state group health insurance plan as a pre-tax benefit for current and retired employees. Chapter 110, F.S., provides the statutory authority for the implementation of health insurance and prescription drug coverage for officers, employees and their dependents of State of Florida agencies. Employees and retirees may choose between a self-insured indemnity plan, called a preferred provider organization (PPO), and one of several approved health maintenance organizations. Sections 110.123 and 110.12315, F.S., describe the coverage available and specify the minimum complement of benefits each approved provider must offer.

Chapter 216, F.S., contains a procedure for the periodic estimation of revenues and expenses for state employee health insurance. The health insurance estimating conference annually reviews the income and claims experience of the self-insurance fund in an attempt to forecast the utilization demands and the legislative funding requirements for the succeeding coverage period. The plan is administered by the Division of State Group Insurance in the Department of Management Services. The PPO Plan provides universal access to employees in all Florida counties. Provider contracts with health maintenance organizations are negotiated separately. Immunization services are currently established in the schedule of minimum benefits for health maintenance organization coverage.

⁵ Pneumococcal Pneumonia, updated December 13, 2004, Department of Health and Human Services National Institute of Allergy and Infectious Diseases, available at www.niaid.nih.gov/factsheets/pneumonia.

⁶ See www.aphanet.org/pharmcare/immunofact

Immunization Coverage within Part VI of the Florida Insurance Code

According to the Office of Insurance Regulation, the newly created statute, s. 627.64194, F.S., would require accident or health insurers to offer optional coverage for immunizations, including those recommended or required for specific international travel.⁷ The optional coverage would be subject to a co-payment and the coverage would not be subject to any deductible co-payment or coinsurance provisions.

By citing the statute in Part VI of chapter 627, the optional coverage provision is applicable only to individual health or accident policies issued by an insurer and is also made applicable to all types of health or accident policy issued to an individual, including specified disease, hospital indemnity, disability income and long term care policies. The mandatory offer would not apply to an insurer issuing a group health policy, covered under Part VII of chapter 627 or to an HMO issuing a group or individual subscriber contract covered under chapter 641 of the Florida Insurance code.

Florida Bright Futures Scholarship

In 1997, the Florida Legislature created the Florida Bright Futures Scholarship Program. The program is funded by the Florida Lottery and provides academic scholarships based on scholastic achievement during high school. Scholarships are awarded to students pursuing postsecondary education. Florida Bright Futures Scholarship Program includes three levels of awards:⁸

- Florida Academic Scholars Award;
- Florida medallion Scholars Award; and
- Florida Gold Seal Vocational Scholars Award

Levels of awards are based grade point average, required credits, community service, and test scores. The December 2006 Bright Futures Estimating Conference projects 146,554 enrollees.

Florida Prepaid College Program

Section 1009.97, F.S., established the Florida Prepaid College Program (Florida Prepaid) to allow Florida residents to pay the cost of higher education in advance at a fixed level and with a statutory state guarantee. The bill addresses the Florida Prepaid College Plan which currently offers three types of tuition plans:

- 4-Year University Tuition Plan – Covers 120 university undergraduate credit hours;
- 2+2 Tuition Plan – Covers 60 community college credit hours and 60 university undergraduate credit hours;
- 2-Year Community College Tuition Plan – Covers 60 community college credit hours.

Currently, there are approximately 800,000 program enrollees.

Enterprise Florida, Inc.

In 1992, Chapter 288, Part VII, F.S., was created establishing Enterprise Florida, Inc. (EFI) as the principal economic development organization for the state. EFI is a public-private partnership and is responsible for leading Florida's statewide economic development efforts. The organization's mission is to diversify the state's economy and create better paying jobs for its citizens by supporting, attracting and helping to create businesses in innovative, high-growth industries. EFI provides a variety of services to companies and focuses on sectors such as: life sciences, information technology, aviation/aerospace, homeland security and defense and financial and professional services. EFI works

⁷ See Office of Insurance regulation Legislative Review 2007, on file with the Committee.

⁸ www.MyFloridaEducation.com/brfuture

with regional and local economic development organizations to assist existing and new business with retention, expansion and creation of businesses.

Enterprise Florida, Inc. is governed by a board of directors, consisting of business, economic and government leaders from the State and is chaired by the Governor.

C. SECTION DIRECTORY:

Section 1. Amends s. 110.123 (h) 2.a, F.S., relating to state group insurance programs.

Section 2. Creates s. 288.9416, F.S., relating to vaccine production facilities and outreach campaign for vaccine production.

Section 3. Renumbers s. 381.005 (3) as s. 381.005 (4), and creates a new s. 381.005 (3), F.S., relating to primary and preventive health services.

Section 4. Creates s. 409.908 (23), F.S., relating to reimbursement of Medicaid providers.

Section 5. Amends s. 465.003 (13), F.S., relating to pharmacy definitions.

Section 6. Creates s. 465.189 (1), F.S., relating to administration of vaccines.

Section 7. Creates s. 627.64194, F.S., relating to coverage for immunizations.

Section 8. Creates s. 1003.22 (10) (c), F.S., relating to district school boards and governing authorities of private schools.

Section 9. Amends s. 1009.53 (5), F.S., relating to Florida Bright Futures Scholarship Program.

Section 10. Amends s. 1009.98 92), F.S., relating to Stanley G. Tate Florida Prepaid College Program.

Section 11. Provides an effective date of July 1, 2007.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

The administration of immunizations to Medicaid recipients will earn \$4,445,088 in federal Medicaid assistance participation.

2. Expenditures:

*The calculations provided below are based on the assumption that all Bright Futures recipients would choose to have the immunizations and that the cost for all students would be comparable to those at the Florida State University, who received their vaccinations through the Leon County Health Department. The recipient data is from the December 2006 Bright Futures Estimating Conference.

		<u>1st Year</u>	<u>2nd Year</u>	<u>3rd Year</u>
Bright Futures Recipients*	Administering meningococcal vaccine to the freshman class of 46,554 students @ \$99 per vaccine	\$4,608,846	\$4,608,846	\$4,608,846
	Administering Hepatitis B series to the freshman class of 46,554 students @ \$108 per series ⁹	\$5,027,832	\$5,027,832	\$5,027,832
	Administering Influenza to the freshman class of 46,554 students @ \$21 per vaccine	\$977,934	\$977,934	\$977,934
	Administering Influenza to 100,000 returning recipients annually @ \$21 per vaccine	\$2,100,000	\$2,100,000	\$2,100,000
Enterprise Florida	Research and analysis, marketing materials and marketing outreach	\$250,000	\$250,000	\$250,000
Department of Health	Mailing of annual reminder notices to 1182 Assisted Living Facilities (ALFs) @ \$0.46 each	\$1,104	\$1,104	\$1,104
	Subtotal General Revenue	\$12,965,716	\$12,965,716	\$12,965,716
Medicaid	Difference between the current administration fee and the increase up to the VFC allowable maximum rate	\$7,810,733	\$7,810,733	\$7,810,733
	Total General Revenue	\$3,365,645	\$3,365,645	\$3,365,645
	Total Trust Fund	\$4,445,088	\$4,445,088	\$4,445,088

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

⁹ The hepatitis B vaccine series consists of three doses spaced out over approximately 6 months. An individual needs to receive the whole series to be protected.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Consumers

Consumers who are at high risk for influenza that may be prevented through immunization may have an increased access to a health care professional who can provide such immunizations, if pharmacists take advantage of the opportunity created in the bill.

Pharmacists

Pharmacists who administer influenza virus immunizations will incur costs for certification and training. According to a representative of the Florida Pharmacy Association, there should be no additional costs to pharmacists for the \$200,000 liability insurance mandated in the bill since most pharmacists carry at least \$1million in such coverage.

Prepaid College Program

According to the Department of Education, the bill increases the amount all future Prepaid College Plans. Typically these costs are passed on to the consumer. However, the bill also impacts all active outstanding contracts. In June 2006, the 2005-2006 the Prepaid College Program Annual Report states there were 790,670 active outstanding contracts. The increase in cost will have to be absorbed by the Prepaid College Board.

There are currently three different types of tuition plans offered under the Florida Prepaid College Program: the tuition plan, a local fee plan, and a dormitory plan. As drafted, the bill requires all plans to cover the cost of the immunizations. Some students may participate in all three plans.

Health and Accident Policy Insurers

The bill requires the immunization coverage to be offered without being subject to policy co-payments or deductibles, which will increase the cost of the benefit. According to Office of Insurance Regulation, the increased claims costs will be passed through to all policyholders in the form of increased premiums. To the extent that policyholders select this optional coverage, utilization of the benefit to prevent illness and disease represents cost avoidance to both the insurer and the policy holder.

D. FISCAL COMMENTS:

Medicaid

According to Agency for Health Care Administration (AHCA), the Florida Medicaid Program currently does not pay for immunizations administered to adults over the age of 20. The Medicaid Program does reimburse for the administration of childhood immunizations.

Individual's ages 0-18 years are provided immunizations through the Vaccine for Children (VFC) Program. The vaccines are provided at no cost to the provider through the VFC Program for 0-18 year olds. Medicaid also reimburses for the cost of the vaccine and the administration of childhood immunizations for 19-20 year olds. The number of projected enrollees is based on the February 9, 2007 Social Services Estimating Conference results.

Medicaid reimburses the administration fee to providers differently for example: physicians \$10, advanced registered nurses and physician assistants \$8, and county health departments and federally qualified health centers \$5. The Federal Register, published on October 3, 1994, provides a maximum regional charge for vaccine administration by state for VFC eligible recipients. According to the Federal Register, the maximum rate for Florida is \$16.06.

The current Medicare reimbursement rate for the administration of influenza and pneumococcal immunizations vary by location: \$18.70 in Ft. Lauderdale, \$19.59 in Miami, and \$17.90 for the remainder of the state. AHCA is concerned that increase in reimbursement rate to the Medicare rate will conflict with the Medicaid reimbursement limitations specified in the Federal Register.

The cost for administering immunizations to adults (20 years or older) is indeterminate. It is impossible ascertain an accurate number of Medicaid eligible adults who would utilize the immunization services. There would be cost associated with the provider reimbursement and the cost for ingredients.

Enterprise Florida Incorporated

According to the Office of Tourism, Trade and Economic Development, the bill will not have a fiscal impact on their agency. However, Enterprise Florida Incorporated has concern that the bill does not reflect costs associated with providing incentives that may be required to encourage pharmaceutical companies, which produce vaccines, to relocate to Florida.

State Group Insurance Program

The Department of Management Services (DMS) manages the state group insurance program that is offered to state employees. Based on a telephone conversation with DMS staff, DMS will incur costs associated with implementing the provisions of the bill. However, they mentioned needing to conduct an actuarial study to determine the increase in the premium amount to provide immunization coverage. DMS estimates that it will cost \$ 40,365 (103,500 insured @ \$0.39 each) to notify the insured of their right to elect coverage for immunization services.

Board of Pharmacy

According to the Department of Health, they may incur minimal costs associated with the Board of Pharmacy's adoption of any rules to implement training requirements for pharmacists to provide immunizations.

Assisted Living Facilities

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

II. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

D. STATEMENT OF THE SPONSOR

No statement submitted.

IV. AMENDMENTS/COUNCIL SUBSTITUTE CHANGES

On March 13, 2007, the Health Innovation Committee adopted one strike-all amendment to the bill. This amendment:

- Creates the Commission on the Study of Biotech Competitiveness within the Governor's Office of Tourism, Trade & Economic Development and provides duties and responsibilities.
- Requires assisted living facilities to offer an immunization program to patients age 65 or older.
- Directs the Department of Health to send annual reminder notices to assisted living facilities regarding immunizations.
- Requires that pneumococcal conjugate vaccine be administered to children less than 2 years of age who are enrolled or are enrolling in child care facilities, family day care or child care homes.
- Authorizes the Department of Health to implement rules regarding pneumococcal conjugate vaccines for children less than 2 years of age.
- Defines "Practice of profession of pharmacy" to include vaccine administration.
- Allow pharmacists to administer vaccines subject to certain criteria such as: pharmacist protocols and requirements regarding supervision, training and immunization certification, continuing education, liability protection, record keeping, and transmission of immunization information to the Department of Health.
- Requires additional insurance option coverage within state accident or health insurance policies and specifies that the additional coverage may be offered for an addition premium not subject to the deductible co-payment or coinsurance provision.
- Removes five sections from the original proposal as follows:
 1. Deletes the requirement that the Department of Management Services establish a schedule of minimum benefits for health maintenance organizations participating in the state group insurance program to include immunization coverage;
 2. Deletes the requirement that Enterprise Florida, Inc. conduct an outreach campaign to encourage pharmaceutical companies to produce vaccines and encourage pharmaceutical companies outside of Florida to establish facilities in Florida;
 3. Deletes the requirement that district school boards and the governing authority of each private school provide information to parents regarding meningococcal disease;
 4. Deletes the requirement that Florida Bright Futures Scholarship awards include immunization coverage for students; and
 5. Deletes the requirement that Stanley G. Tate Florida Prepaid College Program awards include immunization coverage for students.

The bill was reported favorably with one strike-all amendment.