

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 543 Immunization Services
SPONSOR(S): Healthcare Council and Zapata
TIED BILLS: IDEN./SIM. BILLS:

Table with 4 columns: REFERENCE, ACTION, ANALYST, STAFF DIRECTOR. Rows include Committee on Health Innovation, Healthcare Council, Policy & Budget Council, and empty rows.

SUMMARY ANALYSIS

CS/HB 543 creates the Commission on the Study of Biotech Competitiveness within the Governor’s Office of Tourism, Trade & Economic Development

The bill authorizes Florida-licensed pharmacists to administer influenza virus immunizations to adults within the framework of an established protocol under a supervisory Florida-licensed medical or osteopathic physician, or by written agreement with a county health department. Pharmacists seeking to provide immunizations must meet certain qualifications as follows.

A pharmacist:

- may not enter into a protocol unless he or she maintains at least \$200,000 of professional liability insurance and he or she has completed training in influenza virus immunizations;
• must maintain and make available patient records according to established guidelines;
• must forward immunization records to the Department of Health for inclusion in the state registry of immunization information;
• must have the written approval of the pharmacy owner prior to administering immunizations as an employee; and
• must receive certification to administer influenza virus immunizations pursuant to a certification program approved by the Board of Pharmacy.

The bill requires that a copy of the protocol or written agreement to administer influenza virus immunization be submitted to the Board of Pharmacy. The bill specifies that the State Surgeon General may develop a list of additional immunizations that may be administered by pharmacists.

The bill appears to have a fiscal impact on the Governor’s Office of Tourism, Trade & Economic Development.

The bill provides an effective date of July 1, 2007.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Promote personal responsibility—the bill provides pharmacists with the authority to administer influenza virus immunizations to individuals, and thus provide individuals with greater access to immunization health care services.

Provide limited government—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. The commission's membership consists of representatives from the public and private sectors, universities and

Empower families – The bill allows individuals and families who choose to receive influenza virus immunizations from a pharmacist, the opportunity to receive such preventive health care services.

B. EFFECT OF PROPOSED CHANGES:

CS/HB 543 addresses access to immunization services and provides a comprehensive approach to preventing the spread of influenza through increased access to immunization services. The expressed intent of this bill is to prevent the spread of influenza by improving access to immunization services.

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 influenza virus immunizations to adults 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.

The bill creates s. 465.189, F.S., to authorize Florida-licensed pharmacists to administer influenza virus immunizations to adults 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. 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.

Present Situation

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.

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

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

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).

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.

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 April 2006, forty-four states allowed pharmacists to immunize patients.⁵ 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.⁶

In addition to Florida-licensed medical physicians, osteopathic physicians, physician assistants, and nurses, paramedics may administer immunizations under s. 401.272, F.S., Section 401.272, F.S., authorizes a paramedic to administer immunizations after his or her medical director has verified and documented that the paramedic has received sufficient training and experience to administer immunizations.

Confidentiality of and Access to Pharmacy Records

Chapter 465, F.S., provides for the regulation of pharmacists and pharmacies. Section 465.017, F.S., provides that, except upon written authorization of the patient, a pharmacist is authorized to release patient prescription records only to the patient, the patient's legal representatives, and the patient's spouse if the patient is incapacitated, to DOH, or upon the issuance of a subpoena. Section 465.017, F.S., also specifies certain other exceptions for the release of records maintained in a pharmacy relating to the filling of prescriptions and dispensing of drugs. Pharmacists are subject to discipline for using or releasing a patient's records, except as authorized by ch. 465, F.S., and ch. 456, F.S.

C. SECTION DIRECTORY:

Section 1. Creates s. 288.9416, F.S., establishing the Commission on the Study of Biotechnology Competitiveness; creation; organizations.

Section 2. Amends s. 465.003, F.S., relating to pharmacy definitions.

Section 3. Creates s. 465.189, F.S., relating to administration of influenza virus immunizations.

Section 4. Provides an effective date of July 1, 2007.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

⁵ See <http://www.aphanet.org>

⁶ 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.

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

Office of Tourism, Trade and Economic Development (OTTED)⁷

Salaries/Benefits	\$80,000/1 FTE (Development Representative III)
Expenses	\$30,000

The expense amount is an estimate of the cost associated with the commission meetings, any contractual services as needed, production of the final report and related costs.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

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.

D. FISCAL COMMENTS:

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.

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.

⁷ Estimated oversight costs to staff the commission, received by the Office of Tourism, Trade, and Economic Development on April 11, 2007, on file with the Healthcare Council and Health Innovation Committee.

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 favorable with one strike-all amendment.

On **April 4, 1007**, the Healthcare Council adopted 2 amendments to the strike all amendment adopted by the Health Innovation Committee on **March 13, 2007**.

- Removes all references to assisted living facilities to offer an immunization program to patients age 65 or older, and related references to duties of the Department of Health.
- Removes all references to pneumococcal conjugate vaccine administration to children enrolled or are enrolling in child care facilities, family day care or child care homes.
- Removes all references to additional insurance option coverage within state accident or health insurance policies.
- Creates the Commission on the Study of Biotech Competitiveness within the Governor's Office of Tourism, Trade & Economic Development and provides duties and responsibilities.
- 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.

The bill was reported favorable as a Council substitute. The analysis reflects the Council Substitute.