

The Florida Senate
PROFESSIONAL STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

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

Prepared By: Health Regulation Committee

BILL: CS/SB 2022

INTRODUCER: Health Regulation Committee and Senators Bennett and Rich

SUBJECT: Influenza Immunization Services/Pharmacy

DATE: March 21, 2007

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HR	Fav/CS
2.			JU	
3.				
4.				
5.				
6.				

I. Summary:

The bill authorizes a Florida-licensed pharmacist to administer influenza vaccines to adults under a protocol with a supervisory Florida-licensed medical or osteopathic physician or by written agreement with a county health department. The bill establishes requirements for a pharmacist seeking to immunize patients, including approval of the pharmacy owner if the influenza immunizations are performed while the pharmacist is acting as an employee, and certification under a program approved by the Board of Pharmacy, which includes education concerning the safe and effective administration of influenza immunizations and potential allergic reactions to immunizations.

This bill amends s. 465.003 and creates s. 465.189, Florida Statutes.

II. Present Situation:

Influenza and Adult Immunizations

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 after its administration are

¹ See 1999 RAND report prepared for the Centers for Medicare & Medicaid Services, "Interventions that Increase the Utilization of Medicare-Funded Preventive Services for Persons Age 65 and Older."

related to the body's response to the vaccine components at the site of injection. Common reactions may include inflammation at the injection site, which may result in redness, swelling or pain. Less common reactions to the administration of influenza vaccine include fever, malaise, and muscle aches.² Serious immediate allergic reactions to inactivated influenza vaccines are not common, but some serious immediate reactions can occur within a few minutes to a few hours in individuals who likely have allergies to components of the vaccines, which may contain very small amounts of residual egg protein. Immediate allergic reactions can appear in a mild form as itching and hives; however, in the severest form, allergic reactions can result in difficulty breathing, loss of blood pressure, and, while prompt medical treatment is usually effective, even death. The potential side effects of the influenza vaccination must be weighed against the potential benefits of the vaccination, 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. Additionally, as with all vaccines, it is prudent that recipients remain under observation for the first 15-30 minutes after the vaccine is injected to detect and treat any rare, serious allergic reactions and that medications, such as epinephrine and benadryl, used to treat such reactions, be available for immediate use.

The Centers for Disease Control and Prevention (CDC) of the United States Department of Health and Human Services publishes updates on influenza activity periodically in the *Morbidity and Mortality Weekly Report*.³ The Public Health Training Network of the CDC has periodically offered continuing education courses issues relating to influenza immunization.

In addition to influenza, the CDC recommends that adults who lack evidence of immunity or who have specific risk factors take the following vaccines: tetanus, diphtheria, pertussis, human papillomavirus, measles, mumps, rubella, hepatitis A, hepatitis B, and meningococcal.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 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,

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 for example, "Update: Influenza Activity -- United States, February 5-11, 2006," *Morbidity and Mortality Weekly Report* February 24, 2006 vol 55(07); 183-184 <<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5507a5.htm>> (Last visited on March 17, 2007).

⁴ See the CDC's website at <<http://www.cdc.gov/nip/recs/adult-schedule.pdf>> (Last visited on March 17, 2007).

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 influenza 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 Based on a survey of 4,700 pharmacy locations by the American Pharmacists Association, pharmacists are compensated for immunization services by employers, health maintenance organizations, insurance companies, the Medicaid program, the Medicare program, and the patient.

The Medicare program's payment policy for influenza and pneumococcal vaccination has been criticized for being too low and cumbersome by national associations representing health care professionals. A study by the American College of Physicians - American Society of Internal Medicine's Adult Immunization Initiative found that 85 percent of general internists think that reimbursement for immunizations is inadequate and poses a barrier for their practices to continue to provide the service. The associations noted that, "if physicians begin referring patients to other venues for vaccination, it will decrease the likelihood that patients will actually get immunized. Additionally, with the proposed limited reimbursement, non-physician health care professionals providing influenza vaccination may themselves be unable to provide vaccination, be unable to meet increased demands, or be unable to increase their own immunization schedules."⁷ The recognized standard of public health practice is that patients be immunized whenever the physician has the opportunity and the patient needs the vaccine, otherwise patients may be lost to follow-up and not get vaccinated at all.

The Medicare program rates of reimbursement for influenza and pneumococcal immunization had been low, but have recently been increased. The Medicare program will pay a rate for the administration of influenza vaccine which varies by location and ranges from \$14.82 to \$31.01.⁸

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.

⁵ See <http://www.aphanet.org/AM/Template.cfm?Section=Search&template=/CM/HTMLDisplay.cfm&ContentID=6748>> (Last visited March 17, 2007).

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.

⁷ See Association of State and Territorial Health Officials' website at <<http://www.astho.org/>>(Last visited March 17, 2007).

⁸ Source: Centers for Medicare & Medicaid Services.

Confidentiality of and Access to Patient Records

Chapter 456, F.S., specifies the general regulatory provisions for health care professions within the Department of Health (DOH). Section 456.057, F.S., deals with the confidentiality of, and patient's access to, medical records created by specified health care practitioners. "Records owner" is defined to mean any health care practitioner who generates a medical record after making a physical or mental examination of, or administering treatment or dispensing legend drugs to, any person; any health care practitioner to whom records are transferred by a previous records owner; or any health care practitioner's employer, provided the employment contract or agreement between the employer and the health care practitioner designates the employer as the records owner.

For purposes of s. 456.057, F.S., the terms "records owner," "health care practitioner," and "health care practitioner's employer" do not include any of the following persons or entities: certified nursing assistants; *pharmacists and pharmacies*; dental hygienists; nursing home administrators; respiratory therapists; athletic trainers; electrologists; clinical laboratory personnel; medical physicists; opticians and optical establishments; and persons or entities practicing under s. 627.736(7), F.S., relating to personal injury protection claims. These persons or entities are not authorized to acquire or own medical records, but are authorized under the confidentiality and disclosure requirements of s. 456.057, F.S., to maintain those documents required by the part or chapter under which they are licensed or regulated.

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.

III. Effect of Proposed Changes:

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 to adults of influenza vaccines 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.

The bill creates s. 465.189, F.S., to authorize Florida-licensed pharmacists to administer influenza vaccines 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 influenza vaccine. A pharmacist may not enter into a protocol until the pharmacist has completed training in the administration of influenza vaccines as required by s. 465.003, F.S. 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 influenza vaccines while acting as an employee without the written approval of the owner of the pharmacy.

A pharmacist who administers influenza vaccines must maintain and make available patient records in accordance with the standards for patient records under s. 456.057, F.S. These records must be maintained for at least five years.

Any pharmacist seeking to vaccinate patients must be certified to administer influenza vaccinations 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 a pharmacist to attend at least twenty hours of continuing education classes approved by the Board of Pharmacy. The certification program must have a curriculum of instruction concerning the safe and effective administration of influenza vaccines, including, but not limited to, potential allergic reactions to influenza vaccines.

The pharmacist must submit a copy of the protocol or written agreement to administer a vaccine to the Board of Pharmacy.

The effective date of the bill is July 1, 2007.

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 Article VII, Section 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 Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Economic Impact and Fiscal Note:**A. Tax/Fee Issues:**

None.

B. Private Sector Impact:

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

Pharmacists seeking to administer influenza vaccinations will incur costs for certification and training.

C. Government Sector Impact:

The Department of Health may have minimal costs associated with the Board of Pharmacy's adoption of any rules to implement training requirements for pharmacists to provide vaccines.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Summary of Amendments:

None.

This Senate Professional Staff Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.
