

SENATE 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 Care Committee

BILL: SB 570

INTRODUCER: Senator Bennett

SUBJECT: Pharmacy Practice

DATE: March 10, 2006

REVISED: 03/15/06

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Munroe</u>	<u>Wilson</u>	<u>HE</u>	<u>Fav/1 amendment</u>
2.	<u></u>	<u></u>	<u>BI</u>	<u></u>
3.	<u></u>	<u></u>	<u></u>	<u></u>
4.	<u></u>	<u></u>	<u></u>	<u></u>
5.	<u></u>	<u></u>	<u></u>	<u></u>
6.	<u></u>	<u></u>	<u></u>	<u></u>

Please see last section for Summary of Amendments

Technical amendments were recommended

Amendments were recommended

Significant amendments were recommended

I. Summary:

The bill authorizes a pharmacist to administer influenza virus immunizations 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 professional liability insurance, approval of the pharmacy owner if the 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 immunizations and potential allergic reactions to immunizations.

The bill requires the certification for pharmacists to perform inactivated influenza vaccinations to include compliance with specified requirements.

This bill amends section 465.003(13), Florida Statutes.

II. 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 after its administration 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, 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 (CDC) of the United States Department of Health 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.

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

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."

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 10, 2006).

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 September, 2004, 43 states allow pharmacists to immunize patients.⁴ 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.⁵ 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."⁶ 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.

⁴ See <<http://www.aphanet.org/pharmcare/immunofact.html>> (Last visited March 10, 2006).

⁵ 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.

⁶ See Association of State and Territorial Health Officials' website at <http://www.astho.org/templates/display_pub.php?pub_id=334>(Last visited March 10, 2006).

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 \$31.01.⁷

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.

Public Health

The Department of Health (DOH) is responsible for various aspects of public health and must conduct a communicable disease prevention and control program as part of fulfilling its public health mission.⁸ Florida-licensed medical physicians, osteopathic physicians, physician assistants, chiropractic physicians, naturopathic physicians, veterinarians, hospitals, and clinical laboratories that diagnose or suspect the existence of a disease of public health significance must immediately report the fact to DOH.⁹ The Department of Health regulates the packaging, transport, storage, and treatment of biomedical waste.¹⁰ The Department of Environmental Protection regulates onsite and offsite incineration and disposal of biomedical waste.¹¹

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 virus immunizations 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 influenza virus immunizations while acting as an employee without the written approval of the owner of the pharmacy.

A pharmacist who administers influenza vaccine 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.

⁷ Source: Centers for Medicare & Medicaid Services.

⁸ See s. 381.003, F.S.

⁹ See s. 381.0031, F.S.

¹⁰ See s. 381.0098, F.S.

¹¹ See s. 381.0098, F.S.

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 a pharmacist to attend at least 20 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 immunizations, including, but not limited to, potential allergic reactions to immunizations.

The certification to perform inactivated influenza vaccinations must include, but need not be limited to the following compliance criteria: compliance with state law relating to communicable disease and AIDS prevention and control; compliance with state law relating to reporting of diseases of public health significance to DOH; compliance with state law relating to biomedical waste; compliance with all standards of the United States Occupational Safety and Health Administration for management, handling, and disposal of sharps; and completion of and compliance with the Centers for Disease Control Influenza Update for the year in which influenza vaccinations will be offered.

The pharmacist must obtain certification before advertising to the public and administering inactivated influenza vaccinations. The pharmacist must submit a copy of the protocol or written agreement to administer inactivated influenza vaccine to the Board of Pharmacy.

The effective date of the bill is July 1, 2006.

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 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 seeking to administer influenza virus immunizations will incur costs for certification, training, and professional liability insurance.

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 immunizations.

VI. Technical Deficiencies:

None.

VII. Related Issues:

Page 4, lines 9-11 of the bill require the certification for pharmacists to perform inactivated influenza vaccinations to include completion of and compliance with the Centers for Disease Control Influenza Update for the year in which influenza vaccinations will be offered. It is unclear whether this refers to an epidemiology report or a series of continuing education courses that had been provided by CDC on influenza. Additionally, it is unclear whether such continuing education courses providing influenza updates will continue to be available from the CDC in subsequent years.

VIII. Summary of Amendments:

Barcode 593816 by Health Care:

Requires the certification for pharmacists to perform inactivated influenza vaccinations to include completion of and compliance with any continuing education courses on influenza offered by the Centers for Disease Control and Prevention for health care practitioners who administer influenza vaccines.

This Senate staff analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.
