

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: Banking and Insurance Committee

BILL: SB 2296

SPONSOR: Senator Bennett

SUBJECT: Pharmacy Practice

DATE: April 13, 2005

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Munroe</u>	<u>Wilson</u>	<u>HE</u>	<u>Favorable</u>
2.	<u>Emrich</u>	<u>Deffenbaugh</u>	<u>BI</u>	<u>Favorable</u>
3.	_____	_____	_____	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

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.

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

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."

<<http://www.cms.hhs.gov/healthyaging/2a.asp>>.

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.

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 September, 2004, 43 states allow pharmacists to immunize patients.³ 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

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 <<http://www.aphanet.org/pharmcare/immunofact.html>>.

hospitals.⁴ Based on a survey of 4,700 pharmacy locations by the American Pharmacists Association, pharmacists are compensated for immunization services by employers, HMOs, 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."⁵ 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. In Florida, as of January 1, 2005, the Medicare program will pay a rate between \$17.97 to \$19.68 which varies depending on where in the state the immunization was provided.⁶

In addition to Florida-licensed medical physicians, osteopathic physicians, physician assistants, and nurses, paramedics may administer immunizations under s. 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.

Liability Insurance

Presently, there is no statutory requirement that pharmacists carry liability insurance. However, as a practical matter, virtually all pharmacists do carry at least \$1 million of liability coverage, while many carry as much as \$3 million, according to a representative of the Florida Pharmacy Association.

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

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.

⁵ See Association of State and Territorial Health Officials' website at <http://www.astho.org/templates/display_pub.php?pub_id=334>.

⁶ Source: Centers for Medicare & Medicaid Services.

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.

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 effective date of the bill is July 1, 2005.

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 Art. I, s. 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 and training. However, there should not be additional costs to pharmacists for the \$200,000 liability insurance mandated in the bill because virtually all pharmacists carry at least \$1million in such coverage, according to a representative of the Florida Pharmacy Association.

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:

None.

VIII. Summary of Amendments:

None.

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