

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1557 CS Pharmacy Practice
SPONSOR(S): Lopez-Cantera and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 2296

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee	7 Y, 4 N, w/CS	Bell	Mitchell
2) Health & Families Council			
3)			
4)			
5)			

SUMMARY ANALYSIS

HB 1557 with CS amends s. 465.003, F.S., to authorize a pharmacist to administer influenza virus immunizations to adults under protocol with a supervising Florida-licensed physician or by written agreement with a county health department.

The bill requires pharmacists seeking to provide flu immunizations to meet the following qualifications:

- To maintain at least \$200,000 of professional liability insurance;
- To enter into a supervisory protocol with a physician or public health department;
- To have written approval to administer flu vaccines from the pharmacy owner; and
- To have received training and immunization certification approved by the Board of Pharmacy in consultation with the Board of Medicine.

The bill requires that immunization certification for pharmacists includes: at least 20 hours of continuing education classes approved by the Board of Pharmacy, instruction in safe and effective administration of immunizations, and instruction in potential allergic reactions to immunizations.

The supervisory protocol between pharmacist and supervising physician must include specific procedures to address any unforeseen allergic reaction to an immunization, and must require that the patient has had a physical examination by their licensed primary physician within the six months preceding the date of immunization.

The bill addresses scope of practice for pharmacists and access to influenza vaccination for health care consumers.

The effective date of the bill is July 1, 2005

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide Limited Government – The bill increases pharmacists' scope of practice to include immunization of the influenza vaccine under supervision protocols.

Safeguard Individual Liberty – The bill may increase the availability of influenza vaccines for health care consumers. In turn, this may increase influenza vaccination rates in Florida which would decrease the incidence of influenza morbidity, and decrease influenza related mortality.

B. EFFECT OF PROPOSED CHANGES:

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- To enter into a supervisory protocol with a physician or public health department;
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CURRENT SITUATION

Currently, Florida-licensed medical physicians, osteopathic physicians, physician assistants, nurses, and paramedics (after consultation with medical director) may administer immunizations.

Influenza Immunization Overview

Influenza and pneumonia combined represent the fifth leading cause of death in the elderly. Influenza vaccine is the primary method for preventing the flu and its severe complications. Influenza immunizations have been proven to decrease hospitalization and deaths.¹

There are minimal adverse reactions or side effects associated with flu vaccine. The most common adverse reaction to the vaccine is inflammation of the injection site resulting in redness, swelling, or

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

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

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pain immediately after injection. Less common reactions to the administration of flu vaccine may include fever, malaise, and muscle aches.² Serious allergic reactions are usually caused by a reaction to trace amounts of residual egg protein in the vaccine and can occur within minutes up to a few hours after the injection. More serious allergic reactions can range from itching and hives, difficulty breathing, loss of blood pressure, and in rare cases death.

The influenza vaccine is not recommended for people with a history of hypersensitivity to eggs or other components of vaccines. Best medical practice recommends that patients who receive the flu vaccine remain under observation for the first 15-30 minutes after vaccination to detect and treat any adverse reactions. The potential side effects of the vaccination must be weighed against the potential benefits of the vaccination, which include prevention of serious illness, hospitalization, and death.

Influenza in Florida

Healthy People 2010³ designated immunizations as a leading health indicator. Leading health indicators reflect targeted behaviors and disease states that are the leading causes of death nationwide. In Florida, the 2000 death rate for pneumonia and influenza was 20.87 per 100,000 population. Immunization rates for influenza are lower in rural areas and in minority populations. This results in disproportionately higher influenza death rates. Part of the problem is lack of health care access for minority populations and individuals living in rural counties. For instance, influenza vaccination rates for whites were 66 percent in 1997, while for African Americans and Hispanics; rates were only 45 percent and 53 percent respectively.⁴

Pharmacy Practice

Chapter 465, the Florida Pharmacy Act, governs the professional practice 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 professional 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.”
- Monitoring of patient drug therapy, assisting patients in the management of their drug therapy, and communication with the patient’s prescribing health care provider or provider’s agent;
- Any other act, service, operation, research, or transaction related to the pharmaceutical profession; and
- Expressly permits a pharmacist to transmit information from persons authorized to prescribe medicinal drugs to their patients.

Pharmacy Immunizations

As of February 22, 2005, 43 states allow pharmacists to immunize patients.⁵ Several of the states permit pharmacists to immunize for almost all diseases 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

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 *Healthy People 2010* is a comprehensive set of disease prevention and health promotion objectives for the Nation to achieve over the first decade of the new century. Created by scientists both inside and outside of Government, it identifies a wide range of public health priorities and specific, measurable objectives. [<http://healthypeople.gov>]

⁴ Florida Department of Health, [<http://doh.state.fl.us>].

⁵ See [<http://www.aphament.org/pharmcare/immunofact.html>].

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, HMOs, insurance companies, the Medicaid program, the Medicare program, and the patient.

Immunization Reimbursement

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 have been low, but have recently increased. In Florida, as of January 1, 2005, the Medicare program will pay a rate between \$17.97 to \$19.68 which varies by region.

C. SECTION DIRECTORY:

Section 1. Amends s. 456.003, F.S., to add administering influenza vaccine to adults under supervision protocols with a physician to pharmacists' scope of practice.

Section 2. Provides an effective date of July 1, 2005.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

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/templates/display_pub.php?pub_id=334]

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

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

D. FISCAL COMMENTS:

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

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or take an 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 revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

No additional rulemaking authority is required to implement the provisions of this bill. The Board of Pharmacy has sufficient existing rulemaking authority.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

On April 6, 2005, the Health Care Regulation Committee adopted one amendment sponsored by Representative Lopez-Cantera.

- **Amendment 1 – added that supervising protocol set-up between a pharmacist and supervising physician must require that the patient has had a physical examination by their licensed primary physician within the six month preceding the date of immunization.**

This analysis is drafted to the committee substitute.